A PROSPECTIVE, RANDOMIZED STUDY TO COMPARE THE EFFECTIVENESS OF AMBU LARYNGEAL MASK AIRWAY WITH CLASSIC LARYNGEAL MASK AIRWAY IN GYNAECOLOGICAL SURGERIES

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INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE

MADRAS MEDICAL COLLEGE

CHENNAI- 600 003

APRIL 2013

DECLARATION

I hereby declare that the dissertation entitled **"A PROSPECTIVE, RANDOMIZED STUDY TO COMPARE THE EFFECTIVENESS OF AMBU LARYNGEAL MASK AIRWAY WITH CLASSIC LARYNGEAL MASK AIRWAY IN GYNAECOLOGICAL SURGERIES"** has been prepared by me under the Guidance of **Prof.Dr.S.Nellai Kumar ,M.D,D.A,** Professor of Anaesthesiology, Govt. Kasturbai Gandhi Hospital for Women & Children, Madras Medical College, Triplicane, Chennai in partial fulfillment of the regulations for the award of the degree of M.D [Anaesthesiology], examination to be held in April 2013.

This study was conducted at Madras Medical College and Rajiv GandhiGovernment General Hospital, Chennai.

I have not submitted this dissertation previously to any university forthe award of any degree or diploma.

Date :

Place : Chennai **Dr. V.BHARATH**

CERTIFICATE

This is to certify that the dissertation entitled, **"A PROSPECTIVE, RANDOMIZED STUDY TO COMPARE THE EFFECTIVENESS OF AMBU LARYNGEAL MASK AIRWAY WITH CLASSIC LARYNGEAL MASK AIRWAY IN GYNAECOLOGICAL SURGERIES"** submitted by Dr.V.Bharath in partial fulfilment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr. M.G.R. Medical University, Chennai is a bonafide record of the work done by him in the INSTITUTE OF ANAESTHESIOLOGY&CRITICALCARE, Madras Medical College, during the academic year 2010-2013.

DR.M.VASANTHI,M.D,D.A,DNB.,

PROFESSOR AND DIRECTOR
INSTITUTE OF ANAESTHESIOLOGY,
& CRITICAL CARE
MADRAS MEDICAL COLLEGE
CHENNAI – 600 005.

DR. V.KANAGASABAI M.D

DEAN,
MADRAS MEDICAL COLLEGE
& GOVT. GENERAL HOSPITAL,
CHENNAI – 600 003

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Last but not the least, I thank all the patients for willingly submitting themselves for this study.

Above all I pay my gratitude to the lord Almighty for blessing me to complete this work.

CONTENTS

INTRODUCTION

Supraglottic airway devices are devices that ventilate patients by delivering anaesthetic gases and oxygen above the level of vocal cords thereby avoiding the disadvantages of endotracheal intubation. Supraglottic airway devices have the advantages of avoiding laryngoscopy, better tolerance by the patients, lesser hemodynamic perturbations, lesser invasiveness of the respiratory tract, easier placement of the device, airway free from manipulation, lesser complications like sore throat and easier, quicker control of airway even by inexperienced personal.

Laryngeal mask airway is a type of Supraglottic airway device, invented and designed by Dr.Archie I J Brain in London in 1981. Since then it had been used in over 300 million patients worldwide.

The LMA-Classic was introduced into clinical practice since 1988. LMA Classic is an autoclavable laryngeal mask airway which can be reused. It consists of an airway tube which is connected to an inflatable mask with a silicone rim. The LMA Classic, available in sizes 1 to 6, is designed to fit most airways, from neonates through large adults; it is reusable up to 40 times with steam autoclaving. Many

different variants of Classic-LMA have been introduced following its success and popularity. AMBU LMA is one among the variants.

The AMBU LMA is a single use disposable Supraglottic airway device manufactured from polyvinyl chloride. It consists of three main elements which include an airway tube, a mount member and a cuff. The device has a bent forming an angle of 90° which makes it easier to insert as it conforms the human airway anatomy. The cuff is thin and fits well with the hypopharynx. Positioning the cuff properly, places the cuff over the upper oesophageal sphincter and at the base of the tongue rests the proximal end of the cuff. The AMBU LMA does not have aperture bars, meaning the bowl is open and it faces the glottis.

With this background this study was conceptualized to compare the performance of LMA-Classic and LMA-AMBU in minor Gynaecological surgeries.

ANATOMY OF THE UPPER AIRWAY

The upper airway consists of the following components

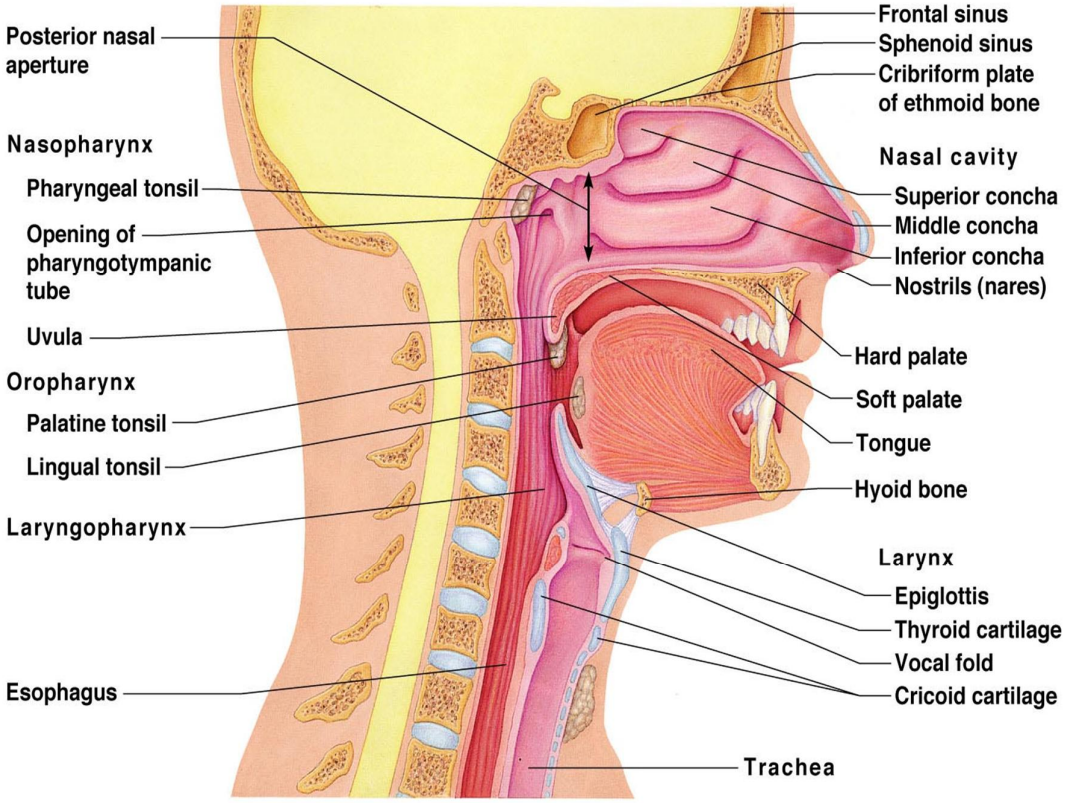
1. Nasal cavity
2. Oral cavity
3. Nasopharynx
4. Oropharynx
5. larynx

Nasal cavity:

The nose warms, filters and humidifies incoming air and is the organ of smell. The nasal cavities extend from naris to the end of the turbinates.

The nasal cavities are divided by the nasal septum. The cribriform plate of ethmoid bone forms the roof of the nasal cavity. From the bony lateral wall of the nasal cavity, originates three turbinates which project into the nasal cavity.

ANATOMY OF THE UPPER AIRWAY



Openings in the lateral wall communicate with the paranasal sinuses. The lining of nasal cavity is very vascular.

Oral cavity:

The oral cavity is bounded by the alveolar arch and teeth anteriorly with hard palate in the front and soft palate posteriorly. The tongue is the chief constituent of the oral cavity, which is bounded by the mandible and teeth. The presence of good mouth opening is essential for many airway procedures. Initial mouth opening occurs due to the rotation within the temporomandibular joint and the later movement occurs due to the sliding or translocation of the condyles of the temporomandibular joint.

Nasopharynx:

Nasopharynx is present behind the nasal cavity and is separated from the oropharynx by the soft palate. During deglutition soft palate prevents the regurgitation of fluid through the nose. The nasopharynx has two important contents. One is the nasopharyngeal tonsil or the adenoids, which is a collection of lymphoid tissue, a part of Waldeyer's ring . Other is the orifice of the pharyngotympanic or the auditory tube.

Oropharynx:

The oropharynx is present behind the mouth and the tongue. It extends from the uvula of the soft palate above to the tip of the epiglottis below. It is bounded anteriorly by the anterior pillar of the fauces. The chief constituent of the oropharynx is palatine tonsils which is one of the constituent of Waldeyer's ring.

Larynx:

The Larynx, which lies at the level of the third through sixth cervical vertebra, serves as the organ of phonation and acts as a valve to protect the lower airways from the contents of the alimentary tract.

The structures which form its framework are the epiglottis, thyroid cartilage, cricoid and the arytenoids. The larynx is slung from the "U" shaped hyoid bone by the thyrohyoid membrane and thyrohyoid muscle.

Behind the root of the tongue lies the leaf shaped elastic cartilage called, the Epiglottis. The hyo- epiglottic ligament attatches the epiglottis to the body of the hyoid bone anteriorly and the thyro-epiglottic ligament connects the epiglottis to the thyroid cartilage immediately above the vocal cords.

The shield-like thyroid cartilage is made up of two lateral plates. These two plates meet in the midline forming the laryngeal prominence, which can be easily visualized in the postpubertal male.

The only cartilage forming complete ring in the entire respiratory tract is the cricoid cartilage. It has a signet ring shape. The cricothyroid membrane attatches the cricoid cartilage to the trachea.

The arytenoids lies one on either side of the posterior surface of the cricoids cartilage. At the apex of the arytenoids lies a nodule called as corniculate cartilage and in the margins of the aryepiglottic folds lies a flank of cartilage called the cuneiform cartilage. These are of no functional importance.

The laryngeal inlet is bounded by the epiglottis, aryepiglottic folds, posterior cartilage, and interarytenoid notch. The vocal cords run between the vocal processes of the arytenoid cartilage and the posterior surface of the thyroid cartilage. The base of the tongue is connected with the lateral border of the epiglottis by the median and the lateral glossoepiglottic folds. The depressions between these two folds is called as the valleculae (often called vallecula).

The laryngeal muscles can be grouped according to their actions on the vocal cords: abductors, adductors, and regulators of tension. The posterior cricoarytenoid muscles abduct the vocal cords. The lateral cricoarytenoid muscles adduct the vocal cords.

The cricothyroid membrane joins the thyroid with the adjacent cricoid cartilage. It is close to the skin, relatively avascular, and the idest gap between the cartilage of the larynx and trachea, so it provides the best access for percutaneous airway rescue techniques.

The trachea extends from the lower edge of the cricoid cartilage to the carina. It consists of U-shaped cartilage joined by fibroelastic tissue and is closed posteriorly by the longitudinal trachealis muscle. The tracheal rings and trachealis muscle are responsible for the characteristic endoscopic appearance of the trachea.

Nerve supply:

The cranial nerve provides sensory supply to the upper airway. The anterior ethmoidal nerve, a branch of Ophthalmic division of the trigeminal nerve and the Sphenopalatine nerve, a branch of maxillary division of the trigeminal nerve innervates the mucous membrane of the

nose. The superior and the inferior surfaces of the hard and soft palate are innervated by the palatine nerves.

The general sensation of the anterior two- thirds of the tongue is provided by the lingual nerve, a branch of mandibular division of trigeminal nerve and taste sensation is provided by the facial nerve. The posterior third of the tongue is innervated by the glossopharyngeal nerve which provides both general and taste sensation.

The roof of the pharynx, the tonsils, and the undersurface of the soft palate are innervated by the glossopharyngeal nerve. The nerve supply for the airway below the glottis is provided by the vagus nerve. Between the epiglottis and the vocal cords the sensory supply is provided by the internal laryngeal nerve, a branch of vagus nerve and the motor supply is provide by the external laryngeal nerve, a branch of vagus nerve. The recurrent laryngeal nerve, a branch of vagus nerve innervates the larynx below the vocal cords.

The recurrent laryngeal nerve innervates the muscles of the larynx except the cricothyroid muscle which is innervated by the external laryngeal nerve.

Damage to the nerves innervating the larynx can lead to a spectrum of disorders. Unilateral denervation of the superior laryngeal nerve causes subtle clinical findings. Bilateral superior laryngeal nerve palsy can lead to hoarseness of voice but the airway control is not jeopardized.

Unilateral recurrent laryngeal nerve palsy causes paralysis of ipsilateral vocal cord, resulting in deterioration in voice quality. Acute bilateral recurrent laryngeal nerve palsy can result in stridor and respiratory distress due to the unopposed tension of the cricothyroid muscles. Chronic bilateral recurrent laryngeal nerve palsy are associated with aphonia and have lesser airway problems due to the development of compensatory mechanisms like atrophy of the laryngeal musculature.

Bilateral vagus nerve injury affects both the superior and the recurrent laryngeal nerves resulting in flaccid, midpositioned vocal cords similar to those seen after administration of succinylcholine. The phonation is severely impaired but the airway is less affected.

Blood supply:

Branches of the thyroid artery provide blood supply to the larynx. The superior laryngeal artery, a branch of the superior thyroid artery, a branch of external carotid artery supplies above the vocal folds. The inferior laryngeal artery, a branch of inferior thyroid artery supplies below the vocal folds.

CLASSIC LARYNGEAL MASK AIRWAY

Classic LMA was the first supraglottic airway device which became available since 1989.

DEVICE DESCRIPTION:

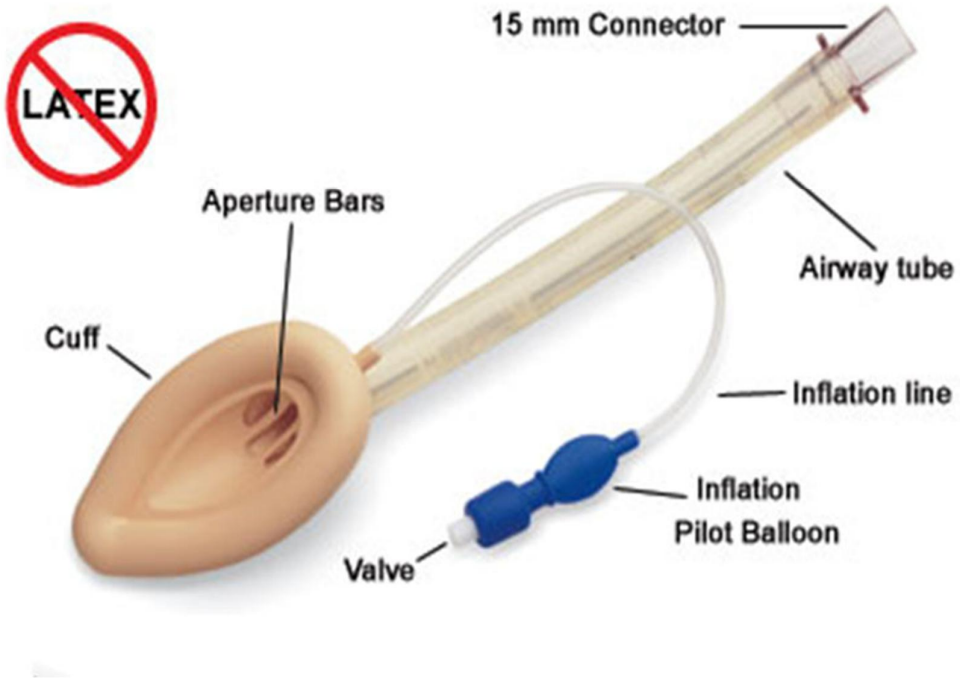
LMA Classic is a reusable device, made up of medical grade silicone and latex free. It can be used 40 times after autoclaving.

Classic LMA has 3 components

1. Airway tube
2. Mask
3. Mask inflation line

The airway tube has a standard 15mm Male adaptor, is a large bore tube fitted to the mask, which has an inflatable cuff. On the distal opening of the tube there are 2 aperture bars for preventing the epiglottis from entering the shaft of LMA leading to obstruction. The mask design of LMA conforms to the contours of the hypopharynx.

CLASSIC LMA


LATEX
15 mm Connector
Aperture Bars
Airway tube
Cuff
Inflation line
Inflation
Pilot Balloon
Valve

INDICATIONS:

1. Elective ventilation : as an alternative to endotracheal intubation for short procedures.

2. Difficult airway: as a rescue device after failed intubation

3. Cardiac arrest: LMA is an acceptable alternative to intubation for airway management in the cardiac arrest patients.

4. Conduit for intubation: in difficult laryngoscopy cases

LMA has role in the management of difficult airway at 5 places, either as:

A. Ventilatory device, or

B. As a conduit to aid tracheal intubation

The 5 places are:

1. LMA as an intubation conduit in the awake intubation limb of the algorithm

2. LMA as an intubation conduit in the non-emergency pathway in

3. anaesthetized patients

4. LMA as an airway device in the non-emergency pathway in anaesthetized patients

5. LMA as an airway device in the emergency pathway (Cannot Ventilate- Cannot Intubate (CVCI)) of the algorithm

6. LMA as a conduit to endotracheal intubation in the emergency pathway (CVCI).

CONTRAINDICATIONS:

Absolute:

1. Cannot open the mouth

2. Complete upper airway obstruction

Relative

A. Increased risk of aspiration:

1. Prolonged bag mask ventilation

2. Morbid obesity

3. Second or third trimester pregnancy

4. Not fasted before ventilation

5. Upper gastrointestinal bleeding

B. Suspected or known abnormal supraglottic airway anatomy

C. Need for high airway pressures

Classic LMA is currently available in 8 sizes

Size of the mask	**Weight (kg)**	**Max cuff inflation volume (ml)**
1	Less than 5	4
1 ½	5 – 10	7
2	10 – 20	10
2 ½	20 – 30	14
3	30 – 50	20
4	50 – 70	30
5	70 – 100	40
6	>100	50

Advantages of LMA compared with face mask

1. Hands free operation
2. Better seal in bearded patients
3. Less cumbersome in ENT surgery
4. Easier to maintain airway
5. Protects against airway secretions
6. Less facial nerve and eye trauma
7. Less operating room pollution

Disadvantages of LMA compared with facemask

1. More invasive
2. More risk of airway trauma
3. Requires new skill
4. Deeper anaesthesia required

5. Requires some temporomandibular joint mobility

6. N_2O diffusion into cuff

7. Multiple contraindications

Advantages of LMA compared with tracheal intubation

1. Less invasive

2. Very useful in difficult intubations

3. Less tooth and laryngeal trauma

4. Less laryngospasm and bronchospasm

5. Does not require muscle relaxation

6. Does not require neck mobility

7. No risk of esophageal or endobronchial intubation

Disadvantages of LMA compared with tracheal intubation

1. Increased risk of gastrointestinal aspiration
2. Less safe in prone or jack knife positions
3. Limits maximum positive pressure ventilation
4. Less secure airway
5. Greater risk of gas leak and pollution
6. Can cause gastric distention

COMPLICATIONS:

The rate of complications due to laryngeal mask insertion was 0.15 % but the rate is likely to be higher in the emergency setting. The complications include:

1. Aspiration of gastric contents
2. Local irritation
3. Upper airway trauma
4. Nerve palsies

5. Mild sympathetic response

6. Obstruction due to improper placement

7. Laryngospasm

8. Pulmonary edema and bronchoconstriction due to positive pressure ventilation

PERFORMANCE TESTS:

Before using the device, the following inspections and tests must be conducted in an area and in an manner consistent with accepted medical practice that minimizes the contamination of the device before insertion.

1. VISUAL INSPECTION:

The surface of the LMA Classic must be examined for damage including cuts, tears, scratches or kinks. The airway tube should not be discoloured.

The interior of the airway tube must be examined to ensure that they are free from blockages and loose particles. If any particle is found

it should be removed. Do not use the device if any blockage or particle can't be removed.

The tube should be flexed upto, but not beyond 180°. Kinking should not occur.

The mask aperture should be gently probed to make sure that it is free from particulate matter.

2. INFLATION AND DEFLATION:

The cuff should be deflated completely. After deflation, check the cuff for spontaneous inflation. If the cuff inflates spontaneously, do not use the airway.

The cuff should be inflated with 50 % more air than the recommended maximum inflation volume. The cuff should hold pressure for at least 2 min. Any herniation, wall thinning , or asymmetry is an indication to discard the LMA.

The balloon should be elliptical, not spherical or irregularly shaped. Excessive pilot balloon width indicates weakness and imminent rupture.

DEVICE INSERTION:

The posterior surface of the mask is lubricated with water soluble jelly just prior to insertion.

Stand behind the patient's head and place the patient's head in the neutral or sniffing position

The tube portion is grasped with the index finger pressing on the point where the tube joins the mask.

With the aperture facing forward, the tip of the cuff is placed against the inner surface of the upper incisors. The tube should be parallel to the floor.

The mask portion is pressed against the hard palate by using index finger.

Maintaining pressure against the palate the mask portion is advanced. A change of direction can be sensed as the mask tip encounters the posterior pharyngeal wall. Swing the device inward with a circular motion, pressing against the hard and soft palate.

The device is advanced into the hypopharynx until resistance is felt.

DEVICE INFLATION:

The cuff should be inflated with air until relevant intra-cuff pressure is reached. The cuff pressure should not exceed 60cm H_2O.

If there is no manometer by hand, inflate with just enough air to achieve a seal sufficient to permit ventilation without leaks.

After inflating the cuff, it should be connected to the anaesthetic breathing circuit. The position of the LMA can be confirmed by :

- A definite end point is noted while inserting the LMA
- While inflating the cuff the LMA rises slightly out of the mouth.
- As the cuff is inflated the anterior neck bulges slightly
- The black line on the back of the LMA remains in the midline
- The cuff of the LMA is not visible in the mouth

AMBU LARYNGEAL MASK AIRWAY

AMBU LMA is a recently introduced disposable supraglottic device. It is made up of polyvinyl chloride. It is made up of 3 parts:

1. Airway tube
2. Mount area
3. Bowl with inflatable cuff

These 3 parts are moulded together in order to prevent their separation. The airway tube has a standard 15mm Male adaptor, with the other end connected to the mount. The airway tube, mount junction is bent 90°, thereby conforming the anatomy of the hypopharynx, pharynx and mouth. This angulation obviates the need of using index finger insertion method used for inserting Classic LMA. There are 3 thickened reinforcement bars at the bent area of the airway tube to maintain the shape during LMA insertion.

INDICATIONS:

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AMBU LMA

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PERFORMANCE TESTS:

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The interior of the airway tube must be examined to ensure that they are free from blockages and loose particles. If any particle is found it should be removed. Do not use the device if any blockage or particle can’t be removed.

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DEVICE INSERTION:

The posterior surface of the mask is lubricated with water soluble jelly just prior to insertion.Stand behind the patient's head and place the patient's head in the neutral position. The tube portion is grasped with hand.

With the cuff facing forward (black line facing the patient's upper lip), the tip of the cuff is placed against the inner surface of the upper incisors. The tube should be parallel to the floor.

The mask portion is pressed against the hard palate by using index finger. Maintaining pressure against the palate the mask portion is advanced.

A change of direction can be sensed as the mask tip encounters the posterior pharyngeal wall. Swing the device inward with a circular motion, pressing against the hard and soft palate.

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REVIEW OF LITERATURE

The literature was searched and reviewed to compare the effectiveness of LMA Classic over LMA Ambu for general anaesthesia for elective surgeries.

1. **A.B.Suzanna**[1], C.Y. Liu, S.W.Syed Rozaidi, J.S.M Ooi compared the ease of insertion, adequacy of seal intraoperatively and postoperative complications between LMA Classic and LMA AMBU in patients undergoing elective general anaesthesia with positive pressure ventilation.

   In this study 118 ASA I & II patients scheduled to undergo elective procedures under general anaesthesia were randomly allocated into receiving either LMA AMBU or the LMA Classic. The intra operative management was identical in both the groups and included induction with propofol/ fentanyl, maintenance with sevoflurane and nitrous oxide oxygen mixture.

   The time for insertion for LMA AMBU group was 35 sec and for LMA Classic it was 40 sec signifying shorter insertion time for LMA AMBU group. The incidence of blood staining was similar.

It was 13 in Classic LMA group and it was 8 in LMA AMBU group. The incidence of sore throat was 20 in the LMA Classic group and it was 9 in the LMA AMBU group signifying lesser incidence of sore throat in the LMA AMBU group.

The study concluded that LMA AMBU took lesser time for insertion and had a superior seal during positive pressure ventilation compared to Classic LMA. AMBU LMA and Classic LMA were comparable in terms of ease of insertion. *(Med J Malaysia Vol 66 No 4 October 2011)*

2. **Cairn A.Hagberg**[2], Frank Samsoe Jensen, Harald V.Genzwuerker, Renee Krivosic-Horber, Bettina U.Schmitz, Jochen Hinkelbein, Marius Contzen, Herve Menu, Karim Bourzoufi evaluated the performance and safety of the AMBU LMA.

   One hundred and eighteen patients of ASA I & II scheduled for elective surgery with general anaesthesia were enrolled in this study. Anaesthesia was induced with alfentanil 20μg/kg or fentanyl 3.5μg/kg followed by propofol 2.5 mg/kg and maintained with propofol and opioids without muscle relaxant.

The study concluded that AMBU LMA was easier and quicker to insert and it resulted in a safer and efficient seal, during positive pressure ventilation in non-paralized patients. *(Anesth Anal 2005;101:1862-6)*

3. **L.Miceli**[3], S.Mattelig, N.Fasano, S.De Lucia, C.Savoia, G.Della Rocca compared Classic LMA with AMBU LMA in terms of insertion time and property of ventilation.

   Twenty two patients of ASA I & II undergoing orthopedic surgery were randomly allocated into two groups (group LMA and group AMBU). Both groups received general anaesthesia with propofol 2.5mg/kg, remifentanyl 0.05-0.5µg/kg/min(continuous infusion) with sevoflurane without muscle relaxant.

   The insertion time was 20.7sec for group LMA and 14.4sec for AMBU LMA group signifying less insertion time for AMBU LMA group. The air leak was 26.1 cmH_2O for group LMA and 24.0 cmH_2O for AMBU LMA group.

The study concluded AMBU LMA had lesser time for insertion and a valid alternative to LMA Classic. *(European Journal of Anaesthesiology: June 2006 - Volume 23 - Issue - p 269).*

4. **C.Y.Wang, LL.Shariffuddin**[21] did a randomized comparison of AMBU LMA with Classic LMA in paralysed anaesthetized patients.

   Forty patients of ASA I & II status scheduled for undergoing elective surgery under general anaesthesia were enrolled for randomized crossover study.

   The mean oropharyngeal leak pressure for AMBU LMA was 19 cmH_2O which was significantly greater than Classic LMA (15 cmH_2O) and the number of attempts for successful insertion was significantly less (50% vs 56%). The time taken for insertion was similar in both the groups.

   The study concluded that both the groups were comparable with respect to trauma to the airway, the quality of fibreoptic view, peak airway pressures and positive pressure ventilation during elective general anaesthesia. *(Anaesthesia. 2008 Jan;63(1):82-5)*

5. **C.S.Strydom**[9], P.J.Le Roux compared the effectiveness between classic LMA, LMA AMBU, LMA Unique and Cobra PLA.

   One hundred and fifteen patients belonging to ASA I to III were taken into the study and were randomized to receive either Classic LMA or one of the four disposable devices. All received standardized anaesthesia with propofol, fentanyl and isoflurane in 40% O_2/N_2O.

   There were no statistical differences in the number of times the airway device had to be changed (p-0.627), ease of insertion (p-0.357) or insertion attempts (p-0.909).

   The study concluded that there was no difference between Classic LMA, LMA Unique, LMA AMBU, Cobra PLA in terms of ease of insertion, number of attempts, patient comfort or airway trauma.*(SAJAA 2008; 14(6): 31-36/Nov/Dec)*

6. **G.Sudhir**[16], D.Redfern, AR.Wilkes, J.E.Hall compared the effectiveness of LMA Classic with LMA AMBU.

   Forty Five patients belonging to ASA I- III were enrolled in this cross over study. All patients received standard total intravenous

general anaesthetic. The AMBU LMA and the Classic LMA were inserted one after other in random order.

The study concluded that the first attempt insertion success rate were comparable between both groups but AMBU LMA had better ease of insertion compared to the Classic LMA. *(Anesthesia: 2005;60,664-7)*

7. **Kristine Faust**[4], Celia D'Errico, Terri Voepel-Lewis, Constance Burke, Vincent Zuellig did a paediatric comparative study between the AMBU LMA and the Classic LMA in terms of ease of insertion and seal pressure.

   One hundred and eighteen children aged between 2-12 yrs were randomly allocated into two groups and received either AMBU

   LMA or Classic LMA for management of the airway . All received induction and maintenance with sevoflurane.

   The study obtained results as 100% ease of insertion for the AMBU LMA group and 93 % for the Classic LMA group. For AMBU LMA, the leak pressure was 21.47 compared to 20.72 for the Classic LMA which was not significant.

The study concluded that AMBU LMA was easier to insert compared to the Classic LMA and was comparable and suitable alternative for use in the children. *(Anesthesia & Analgesia, Dec 2005)*

8. **Harald V Genzwuerker**[8] compared the effectiveness between Classic LMA and AMBU LMA in paediatric patients undergoing ambulatory surgery.

   One hundred children of ASA I & II aged 2-8 yrs undergoing elective ambulatory procedures were enrolled in the study and were randomly allocated into two groups.

   The study concluded that Classic LMA and AMBU LMA were comparable with respect to the number of insertion ttempts and the airway seal quality. *(ASA 2007)*

9. **Gernoth.C**[10], Jandewerth.O, Contzen.M, Hinkelbein.J, Genzwuerk.H.V compared the ease of insertion and the quality of airway seal between LMA AMBU and LMA Classic in patients with simulated cervical spine immobility.

Sixty patients who were scheduled to undergo elective day care procedures were randomly allocated into two groups – ALM (LMA AMBU) and LMC (LMA CLASSIC). Anaesthesia management was similar in both the groups.

The time taken for insertion of the device in the ALM was 15.6 +/- 4.4 and in the LMC group it was 15.5 +/- 4.9 seconds. Airway leak pressure in the ALM group were 25.6 +/- 5.2 cmH_2O and for LCM group it was 26.5 +/- 6.5 cmH_2O.

The study concluded that the ease of insertion, airway seal and post operative complaints were comparable in both the groups. *(EJA, May 2005- volume 22- Issue- p 76)*

10. **J.Jakobsson**[15], Z.Turan, A.Doolke, G.B.Saros compared the effectiveness of Classic LMA, AMBU LMA and intersurgical mask.

One hundred and eighty nine patients scheduled to undergo short procedures under positive pressre ventillation were randomly allocated into three groups to receive either LMA Classic or AMBU LMA or intersurgical mask.

The study concluded that the AMBU LMA was easier to use and all the three airways, LMA Classic, AMBU LMA and Intersurgical airway were comparable with respect to number of attempts for first insertion and complications. *(EJA, June 2007- Volume 24- Issue – p 11-12)*.

11. **Daryl Lindsay Williams**[5], James M.Zeng, Karl D. Alexander, and David T. Andrews compared the effectiveness of AMBU LMA with LMA Unique.

    Eighty two patients were enrolled in the study and randomly divided into two groups of LMAU group to receive LMA Unique and AMBU group to receive AMBU LMA. All patients a standardized anaesthesia management.

    The LMAU group had a mean cuff leak pressure of 15cm H_2O and the AMBU group had a mean cuff leak pressure of 20 cm H_2O with $p = 0.001$ which is statistically significant.

The study concluded that AMBU LMA provided better cuff leak pressure compared to the LMA Unique. Both the airway devices were comparable in terms of time for insertion, success rate and complications. *(Anaesthesiology Research and Practice, Volume 2012, Article ID 405812)*

AIM OF THE STUDY

Aim of the study is to compare the effectiveness of Classic Laryngeal Mask Airway with AMBU Laryngeal Mask Airway in respect to the following parameters

1. Ease of insertion of airway device
2. Number of attempts for insertion of airway device
3. Time taken for insertion of airway device
4. Hemodynamic response to Insertion
5. Blood staining of devices
6. Incidence of complications

MATERIALS AND METHODS

It was a prospective, randomized, single-blinded, case-controlled study conducted in the Department of Anaesthesiology, Kasturba Gandhi Hospital, Chennai. 60 adult patients satisfying the inclusion criteria were enrolled in the study.

INCLUSION CRITERIA:

- Age: 18 yrs and above
- Weight : BMI < 30kg/m^2
- ASA : I & II
- Elective Surgery
- Mallampatti scores : I & II
- Patients given valid informed consent

EXCLUSION CRITERIA:

- Not satisfying inclusion criteria
- Patients posted for emergency surgery
- Patients with difficult airway

- ❖ Lack of written informed consent
- ❖ Pregnant female
- ❖ History suggestive of Gastro oesophageal reflux disease/ Hiatal hernia
- ❖ Poor lung compliance such as pulmonary fibrosis

MATERIALS:

- ❖ LMA Classic 3 & 4
- ❖ LMA AMBU 3 & 4
- ❖ 20 ml syringe
- ❖ Lubricant jelly
- ❖ Drugs: glycopyrolate, fentanyl, propofol, sevoflurane,ondansetron
- ❖ Moitors : ECG, Pulse oximetry, Capnography, NIBP
- ❖ Weighing machine calibrated to 1kg

STUDY OUTCOME:

1. Ease of Insertion of airway device:

   The ease with patient were intubated was judged subjectively on nominal scale as “easy (1)” and “difficult (2)”

2. No of Insertion attempts:

   The no. of attempts required for successful insertion was recorded. A “failed attempt” was defined as removal of the device after third attempt and requiring other methods to secure the airway.

3. Time taken for insertion:

   It is defined as the time elapsed between picking up of airway device in the hand until the presence of square wave capnography trace.

4. Haemodynamic response:

   The Heart rate and blood pressure of the patients were recorded before insertion, 1 min after insertion, 2 min after and 5 min post insertion of the device.

5. End tidal carbondioxide:

   The EtCO2 was measured after device insertion

6. Blood staining of the device:

   The presence or absence of blood on the device was noted at the end of surgery following removal of the device after adequate recovery.

7. Incidence of complications:

   After removal of the device following adequate recovery patients were asked whether they experienced sore throat.

   Sore throat was defined as a constant pain or discomfort in the throat independent of swallowing.

CONDUCTION OF THE STUDY

After obtaining institutional ethical committee clearance, all patients scheduled for elective minor gynaecological surgeries were screened for any comorbid illness and difficult airway. Age, height and weight were assessed. 60 patients satisfying the inclusion criteria were enrolled in the study. A written informed consent was obtained and the

patients were randomly allocated into two groups, LMA-C and LMA-A, with 30 each by using closed envelop method. The size of the airway was chosen in accordance to the manufacturers recommendations.

All patients were premedicated with Inj.glycopyrolate 0.2mg iv in the pre anaesthesia room. The patients were shifted inside the operating room and placed in supine position. Non invasive blood pressure monitor, Pulse oximetry and ECG monitor were connected. Baseline Heart rate, Blood pressure and SpO_2 were recorded.

All patients were preoxygenated with 100% oxygen at a flow rate of 6L/min for 3 minutes by using appropriate anatomical face mask. Patient was induced with Inj,Fentanyl 2μ/kg and Inj. Propofol 2mg/kg. Patient was ventilated with nitrous oxygen mixture 4L:4L with sevoflurane 4% for 1 min.

In LMA-C group, the appropriate sized LMA-Classic was inserted in sniffing position as per manufacturers recommended technique and is taped in position. The cuff was inflated with air. The air inflated was enough to provide a seal which can permit ventilation without any leaks. The end tidal carbon dioxide trace was noted and the initial square wave waveform was taken as an indicator of effective ventilation.

Else, another insertion attempt was tried after removing the device, with a maximum of 3 attempts allowed. The ease of insertion, no of attempts taken for successful placement and the time taken for insertion were recorded in both the groups.

In LMA-A group, the above procedure was performed similarly. In both groups, anaesthesia was maintained with 2% sevoflurane and N_2O: O_2 at 2:1 ratio. No muscle relaxant was used. The Heart rate and Blood pressure were recorded 1 min after insertion, after 2 minutes and 5 minutes post insertion.

At the end of the surgery, after thorough oral suctioning, the airway device was removed upon return of spontaneous breathing and eye opening of the patient. After removing the airway, it was inspected for any blood on the device which is an indication of airway trauma.

The following complications were recorded – cough, stridor, laryngospasm and hypoxia. Patients were evaluated for the presence of sore throat before leaving the operating room and 2 hrs post operatively in the recovery room.

All recorded data were analysed with SPSS software for V Windows version 15.0. The quantitative datas were analysed by students t-test and the qualitative data by chi-square test. Power analysis was calculated using Minitab for windows and the power was well above the accepted level of 80%.

OBSERVATION AND RESULTS

This prospective, randomized, comparative, single blinded case control study compared LMA Classic with LMA AMBU in 60 adult females undergoing minor gynaecological surgeries.

Results are expressed as mean and standard deviation. All statistical analyses were carried out using SPSS for windows version 15.0. The t-test was used for comparison of quantitative variants. Qualitative variants were compared using the chi-squared test. A, ‘p’ value of less than 0.05 was considered statistically significant.

Table: 1 Demographic profile: Age

Group	No of patients	Mean	SD	p value
LMA C	30	34.6	9.4	0.796 ***Not significant***
LMA A	30	35.2	8.4	

The mean age of group LMA C (Classic LMA) is 34.6 and group LMA A (AMBU LMA) is 35.2 . The data is statistically not significant (p = 0.796) and both the groups are comparable with respect to the demographic profile : age.

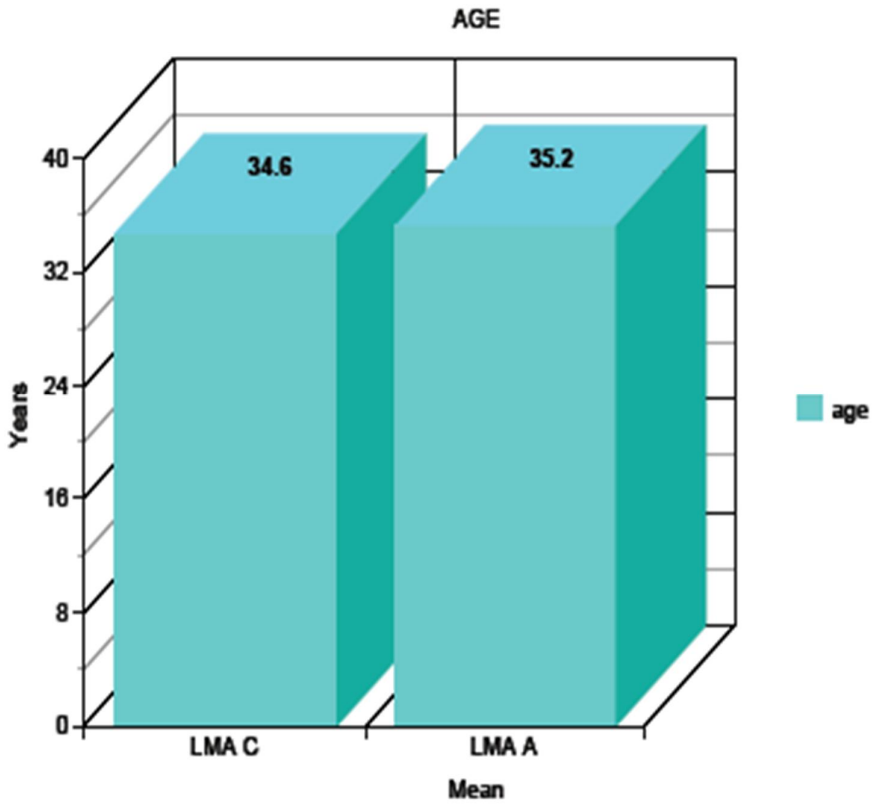

AGE
40
32
24
16
8
0
Years
34.6
35.2
LMA C
LMA A
Mean
age

Table: 2 Demographic profile: Weight

Group	Number of patients	Mean	SD	p value
LMA C	30	53.63	7.11	0.790 ***Not significant***
LMA A	30	54.16	7.47	

The mean weight of Group LMA C is 53.63 and for Group LMA A is 54.16. The data is statistically insignificant (p = 0.790) and both the groups are comparable with respect to the demographic profile : weight.

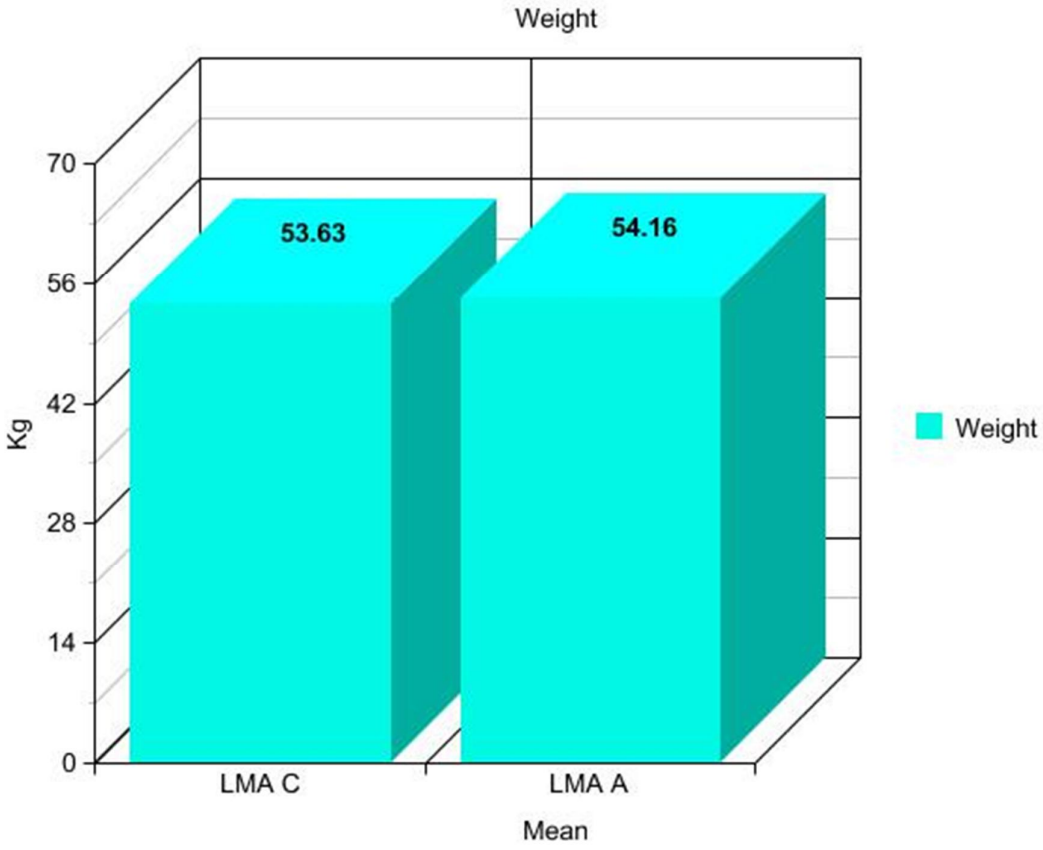

Weight
70
56
42
28
14
0
Kg
53.63
54.16
LMA C
LMA A
Mean
Weight

Table: 3 Demographic profile: Height

Group	Number of patients	Mean	SD	P value
LMA C	30	152	5.41	0.416 ***Not significant***
LMA A	30	153.1	4.97	

The mean height of Group LMA C is 152 and for Group LMA A is 153.1. The data is statistically insignificant (p = 0.416) and both the groups are comparable with respect to the demographic profile: height.

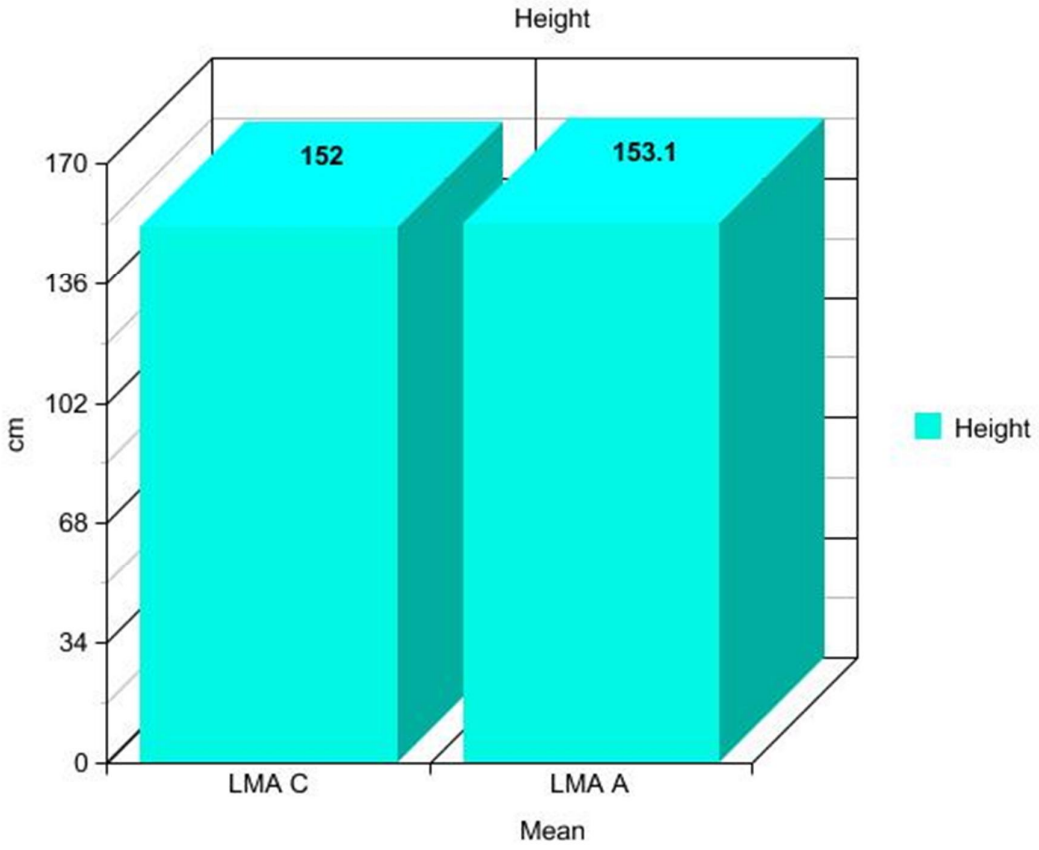

Height
152
153.1
170
136
102
68
34
0
cm
LMA C
LMA A
Mean
Height

Table: 4 Demographic profile: BMI

Group	Number of patients	Mean	SD	P value
LMA C	30	23.30	2.594	0.652 ***Not significant***
LMA A	30	23.03	2.077	

The mean BMI of group LMA C is 23.30 and group LMA A is 23.03. The data is statistically not significant (p = 0.652) and both the groups are comparable with respect to the demographic profile: BMI.

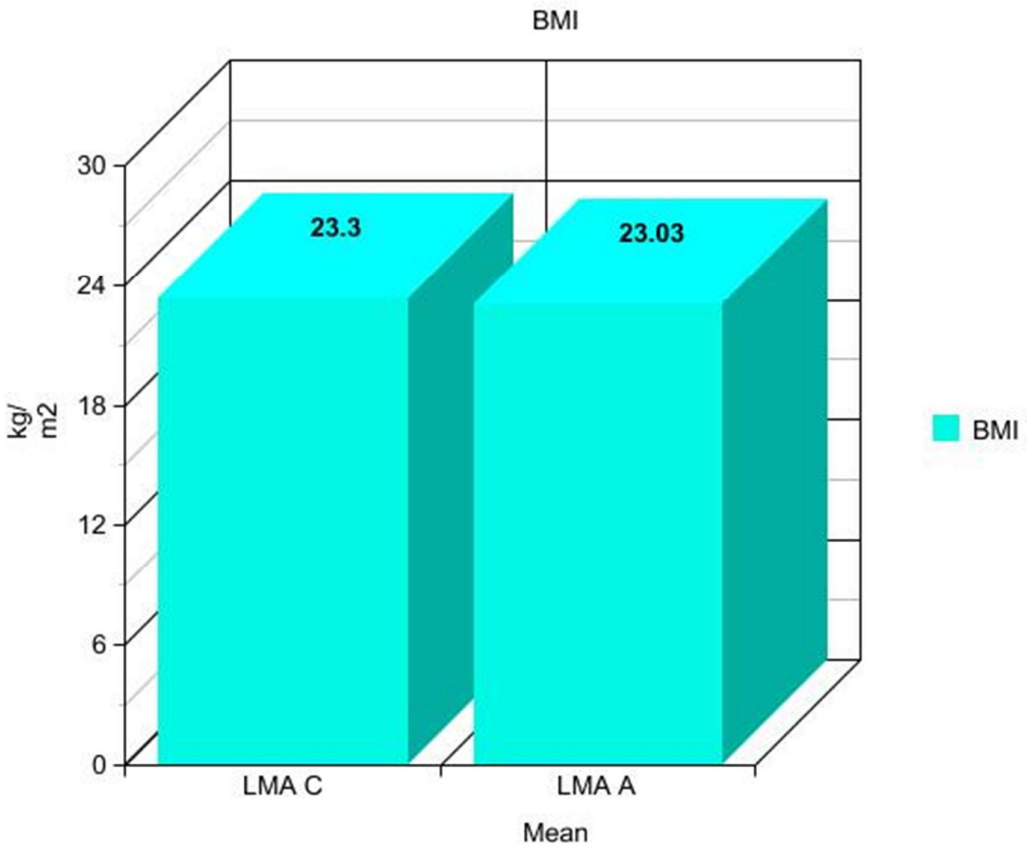

BMI
30
24
18
12
6
0
kg/
m2
23.3
23.03
LMA C
LMA A
Mean
BMI

Table: 5 Demographic profile: ASA PS Status

Group	ASA I		ASA II		P value
	Number of patients	**%**	**Number of patients**	**%**	1.000 ***Not significant***
LMA C	24	80	6	20	
LMA A	24	80	6	20	

In Group LMA C, 24 patients were ASA I and 6 were ASA II patients. In Group LMA A there were 24 patients in ASA I and 6 patients in ASA II. The data is statistically not significant (p = 1.000) and both the groups are comparable with respect to ASA Physical Status.

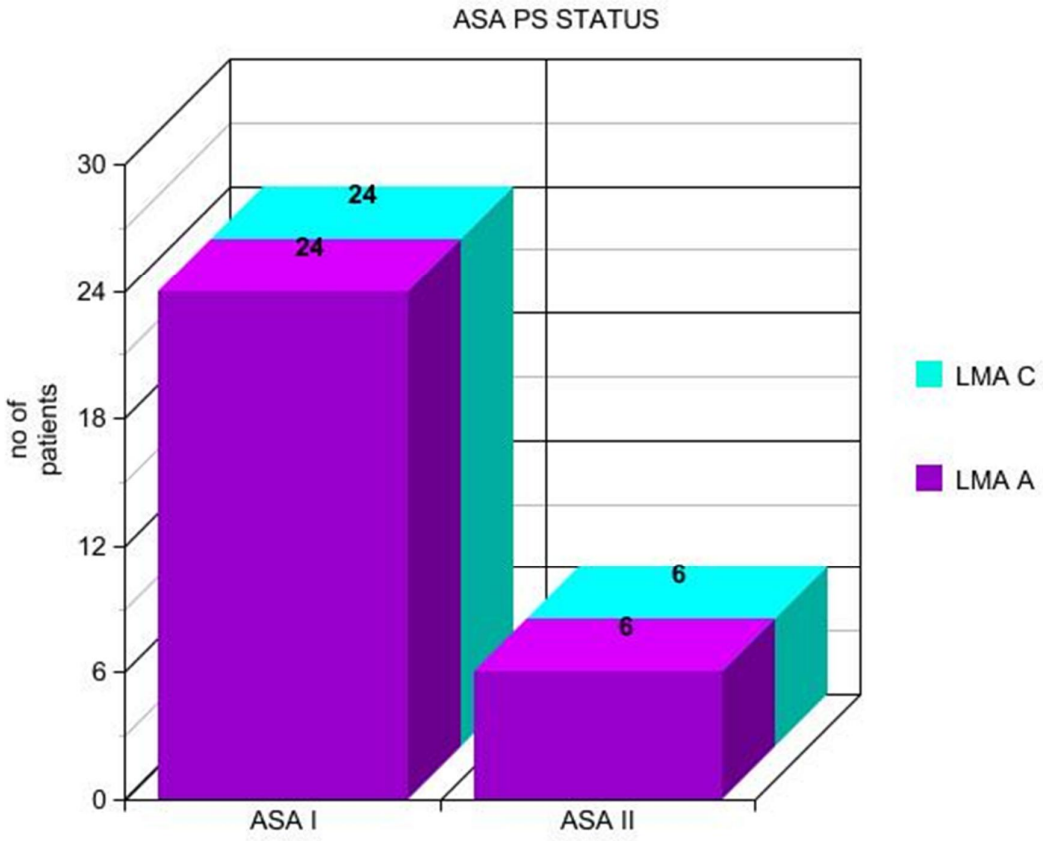

ASA PS STATUS
30
24
18
12
6
0
no of patients
24
24
6
6
ASA I
ASA II
LMA C
LMA A

Table: 6 Demographic profile: MPC

Group	MPC I		MPC II		P value
	Number of patients	**%**	**Number of patients**	**%**	1.000 ***Not significant***
LMA C	23	76	7	24	
LMA A	23	76	7	24	

23 patients in Group LMA C were MPC I and 7 patients were MPC II. In group LMA A, 23 patients were MPC I and 7 patients were MPC II. The data is statistically not significant (p = 1.000) and both the groups are comparable with respect to MPC.

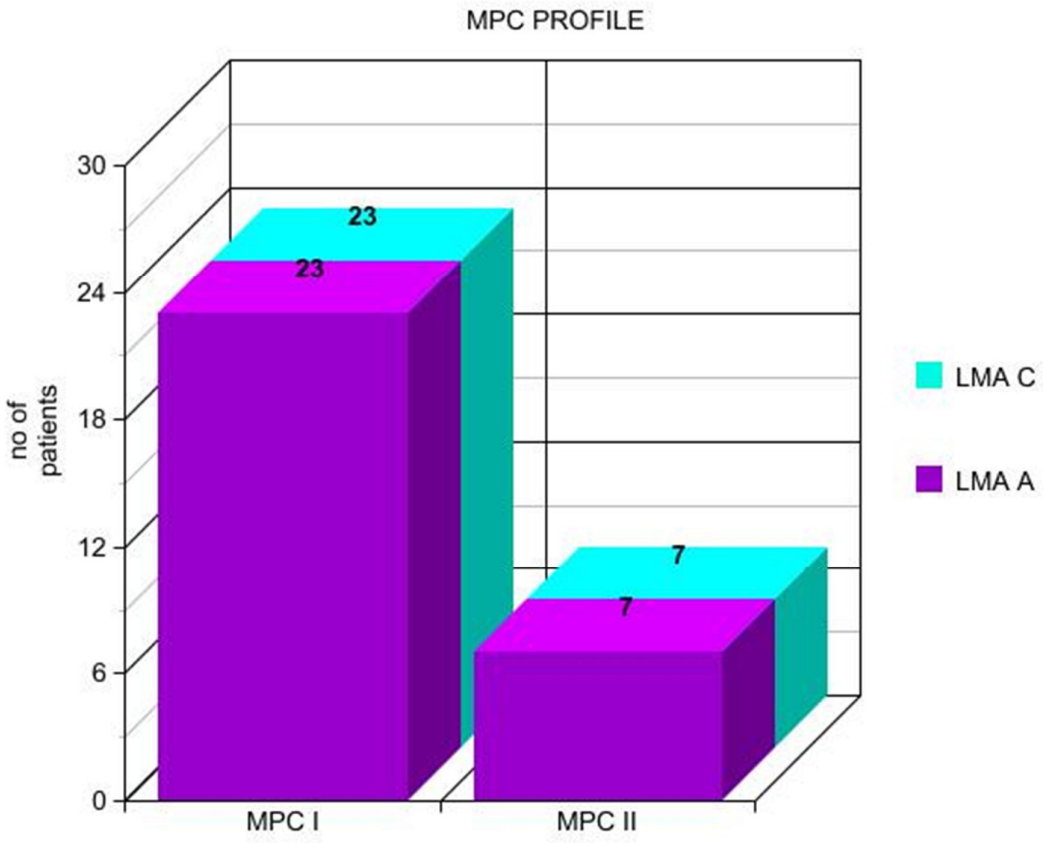

MPC PROFILE
30
24
18
12
6
0
no of patients
23
23
7
7
MPC I
MPC II
LMA C
LMA A

Table: 7 $EtCO_2$

Group	Number of patients	Mean	SD	P value
LMA C	30	36.97	0.85	0.835 ***Not significant***
LMA A	30	37.03	1.52	

The mean $EtCO_2$ for group LMA C is 36.97 and the mean EtCO2 for group LMA A is 37.03. Student's t test reveals p value of 0.835 which is statistically not significant. This indicates both the group are comparable with respect to $EtCO_2$ measurement.

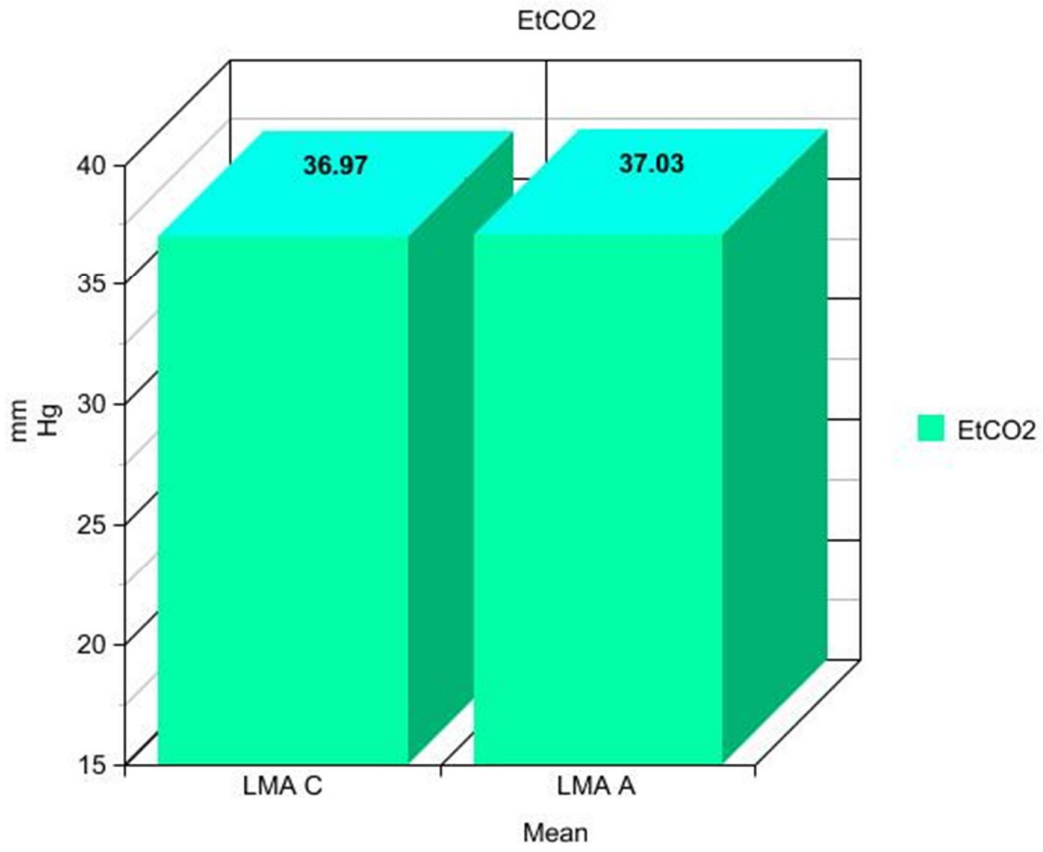

EtCO2
36.97
37.03
40
35
30
25
20
15
mm Hg
LMA C
LMA A
Mean
EtCO2

Table: 8 Ease of insertion of airway device

Group	Number of patients	Easy		Difficult	
		NO	%	NO	%
LMA C	30	19	63	11	37
LMA A	30	27	90	3	10
p value (***significant***)		0.0126		0.0067	

By using LMA Classic, 19 cases were inserted easily and 11 cases were inserted with difficulty. By using AMBU LMA 27 cases ere inserted easily and 3 cases were inserted with difficulty.

Qualitative data values are compared by chi-square test. Statistical analysis reveals P value of 0.0126 for easy insertion and a p value of 0.0067 for difficult insertion which are statistically significant.

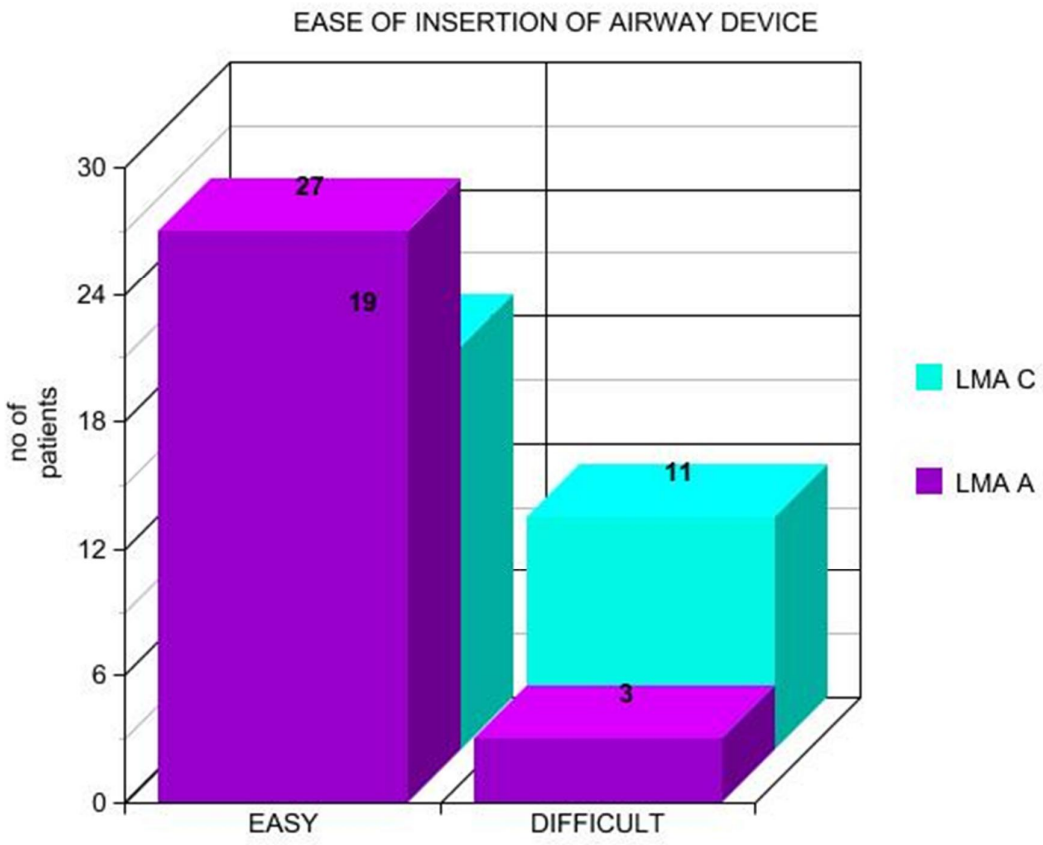

EASE OF INSERTION OF AIRWAY DEVICE
no of patients
30
24
18
12
6
0
27
19
11
3
EASY
DIFFICULT
LMA C
LMA A

Table: 9 No of attempts

Group	Number of patients	Success in				P value
		1st attempt	%	2nd attempt	%	0.0281 *significant*
LMA C	30	25	83.3	5	16.7	
LMA A	30	28	93.3	2	6.7	

LMA Classic insertion was successful in 25/30 in first attempt while 1 patient required second attempt. AMBU LMA insertion was successful in 28/30 patients in the first attempt.

Statistical analysis reveals P value of 0.0281 which is statistically significant. The two groups are statistically significant in number of attempts required for successful insertion.

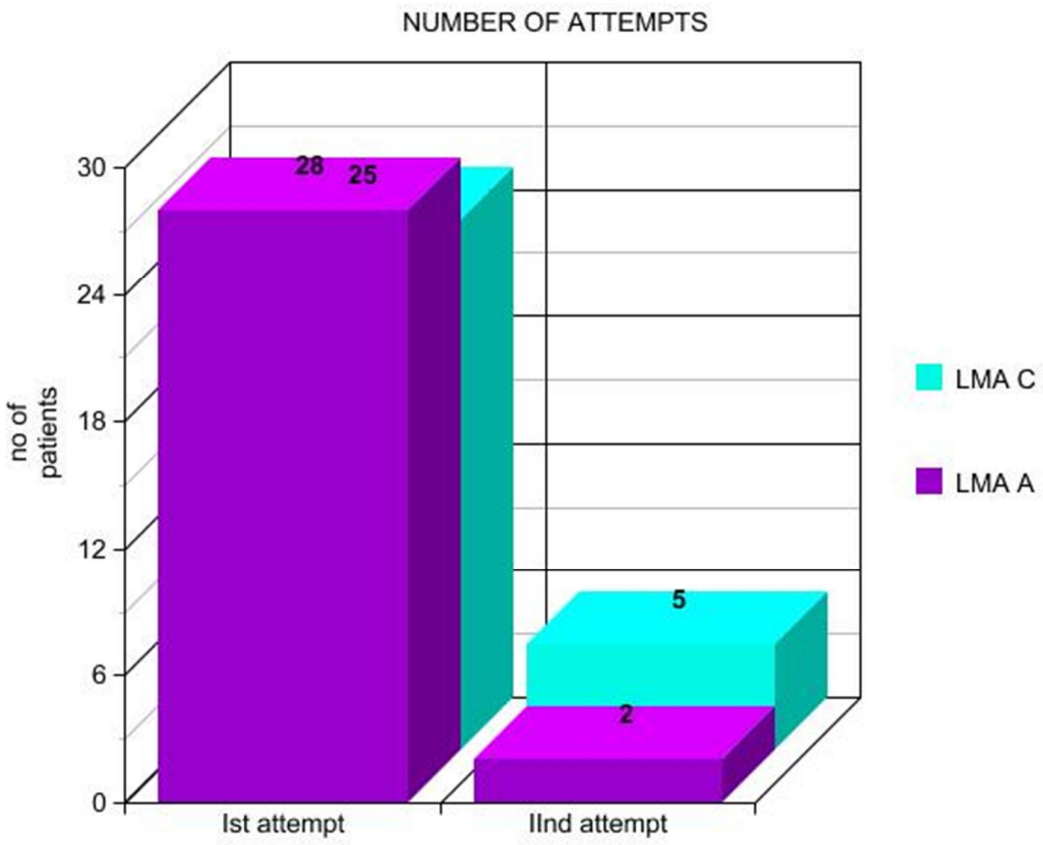

NUMBER OF ATTEMPTS
30
24
18
12
6
0
no of patients
28
25
5
2
Ist attempt
IInd attempt
LMA C
LMA A

Table: 10 Time taken for insertion

Group	Number of patients	Mean	SD	P value
LMA C	30	24.77	2.54	<0.001 ***significant***
LMA A	30	15.2	2.7	

The mean time taken for insertion in LMA A is 15.2 seconds and the mean time taken for the insertion in LMA C is 24.77 seconds.Student's t test reveals p value of < 0.001 which is statistically significant.

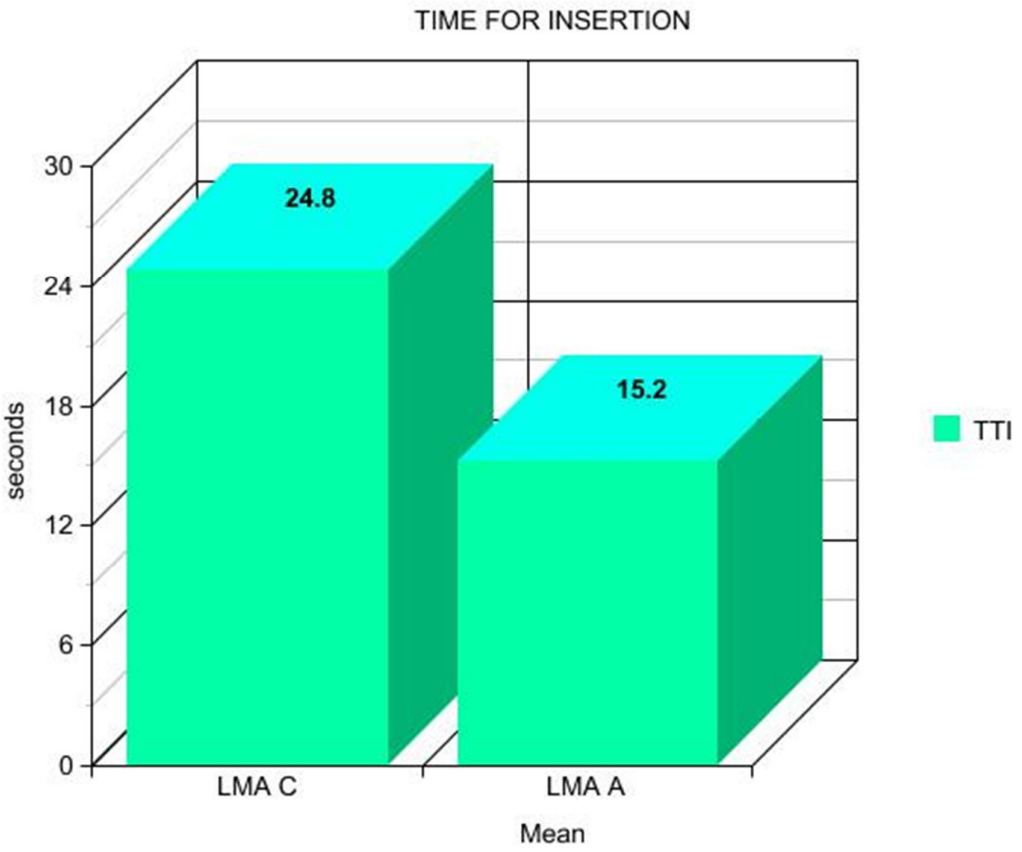

TIME FOR INSERTION
30
24
18
12
6
0
seconds
24.8
15.2
LMA C
LMA A
Mean
TTI

Table: 11 Haemodynamic tesponses

Table: 11a Heart Rate

	Group	**Number of patients**	**Mean**	**SD**	**P value**
Baseline	LMA C	30	76.9	4.52	0.586 ***Not significant***
	LMA A	30	76.2	4.53	
Post insertion at 1 min	LMA C	30	79.2	6.6	0.085 ***Not significant***
	LMA A	30	77.0	6.2	
Post insertion at 2 min	LMA C	30	79.8	7.4	0.123 ***Not significant***
	LMA A	30	76.8	7.6	
Post insertion at 5 min	LMA C	30	76.6	4.9	0.014 ***Significant***
	LMA A	30	73.4	4.8	

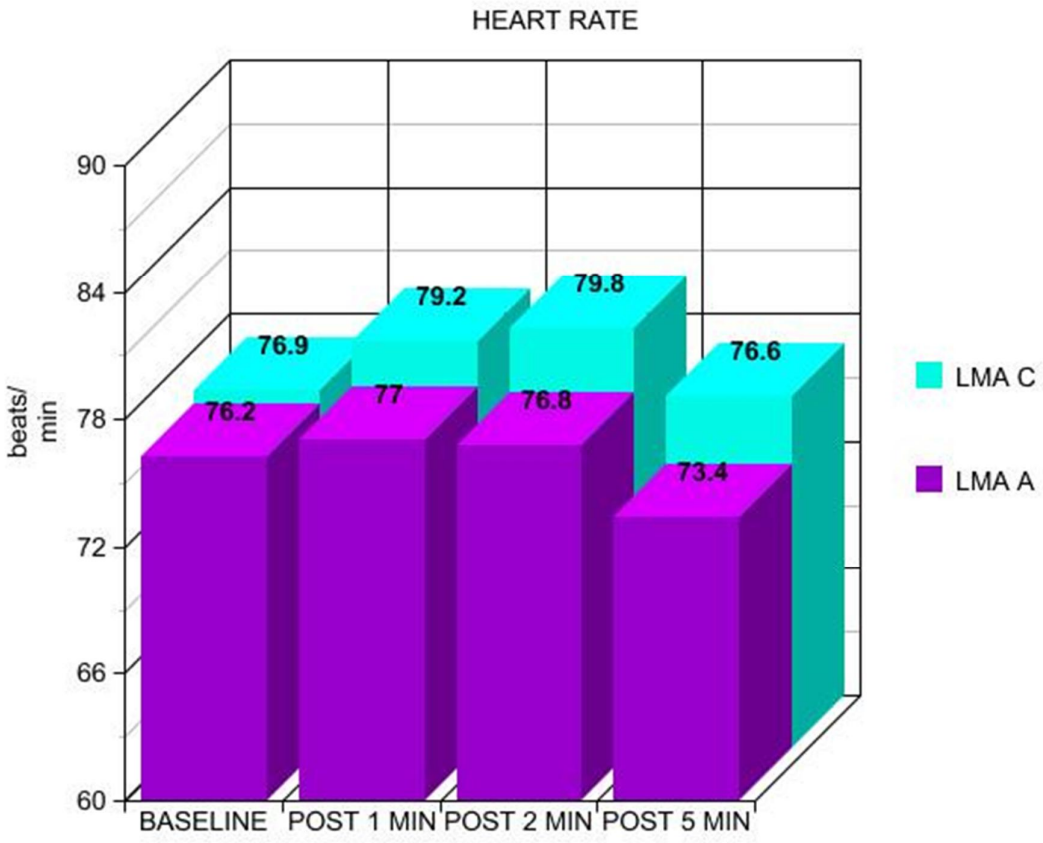

HEART RATE
90
84
78
72
66
60
beats/
min
76.9
79.2
79.8
76.6
76.2
77
76.8
73.4
BASELINE
POST 1 MIN
POST 2 MIN
POST 5 MIN
LMA C
LMA A

Table: 11b Systolic Blood Pressure

	Group	Number of patients	Mean	SD	P value
Baseline	LMA C	30	119.87	6.43	0.47 ***Not significant***
	LMA A	30	121.2	7.68	
Post insertion at 1 min	LMA C	30	120.1	8.27	0.432 ***Not Significant***
	LMA A	30	118.03	11.7	
Post insertion at 2 min	LMA C	30	119.93	10.62	0.044 ***Significant***
	LMA A	30	114.17	11.04	
Post insertion at 5 min	LMA C	30	114.5	7.03	0.043 ***Significant***
	LMA A	30	109.47	11.32	

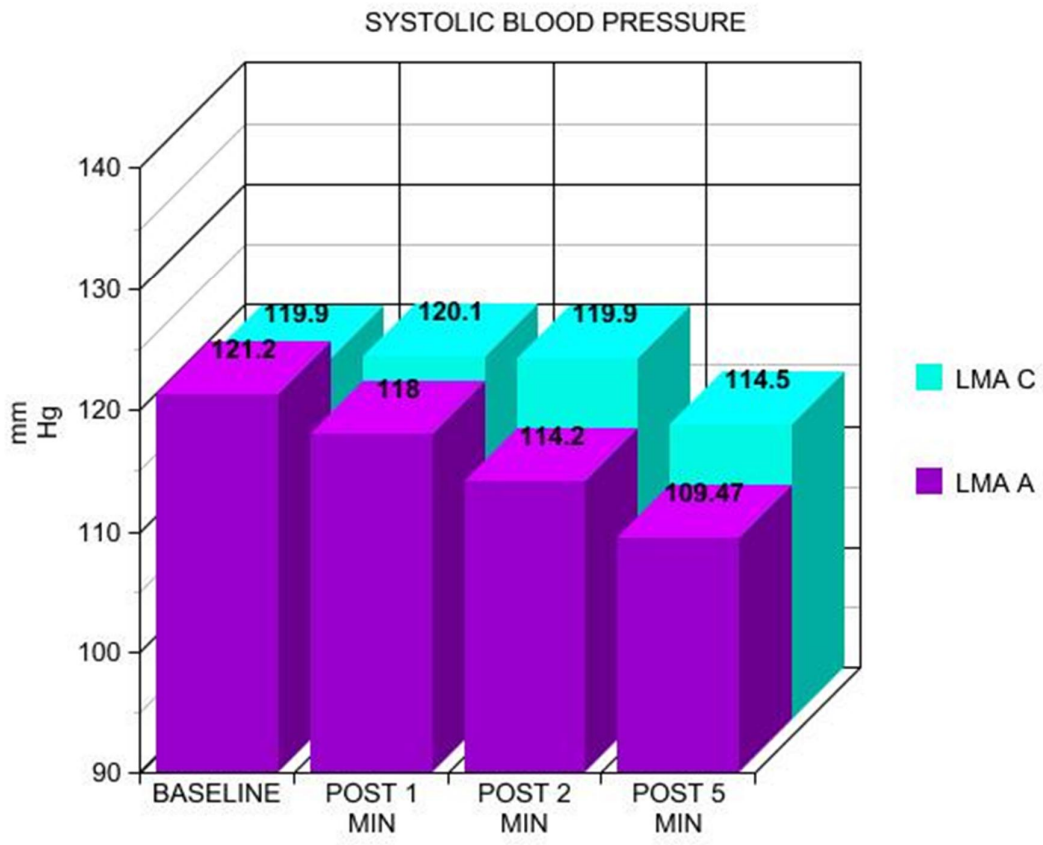

SYSTOLIC BLOOD PRESSURE
mm Hg
140
130
120
110
100
90
119.9
120.1
119.9
121.2
118
114.2
114.5
109.47
BASELINE
POST 1 MIN
POST 2 MIN
POST 5 MIN
LMA C
LMA A

Table: 11c Diastolic Blood Pressure

	Group	Number of patients	Mean	SD	P value
Baseline	LMA C	30	77.83	2.68	0.81 ***Not significant***
	LMA A	30	77.6	4.3	
Post insertion at 1 min	LMA C	30	78.53	4.4	0.051 ***Not Significant***
	LMA A	30	75.8	6.1	
Post insertion at 2 min	LMA C	30	78.4	5.32	0.006 ***Significant***
	LMA A	30	73.67	7.4	
Post insertion at 5 min	LMA C	30	76	3.67	0.001 ***Significant***
	LMA A	30	71.37	6.2	

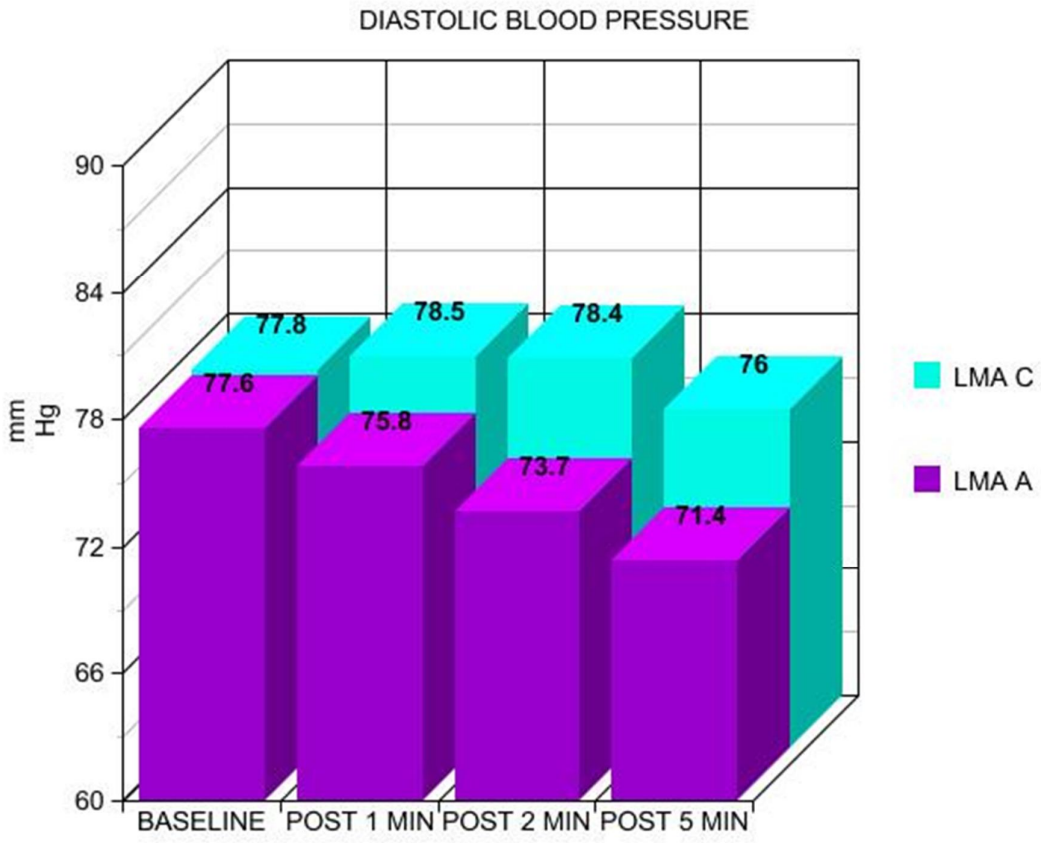

DIASTOLIC BLOOD PRESSURE
mm Hg
90
84
78
72
66
60
77.8
78.5
78.4
76
77.6
75.8
73.7
71.4
BASELINE
POST 1 MIN
POST 2 MIN
POST 5 MIN
LMA C
LMA A

Table: 11d Mean Arterial Pressure

	Group	Number of patients	Mean	SD	P value
Baseline	LMA C	30	92.1	3.9	1.000 ***Not significant***
	LMA A	30	92.1	5.1	
Post insertion at 1 min	LMA C	30	93.0	6.3	0.063 ***Not Significant***
	LMA A	30	89.5	8.1	
Post insertion at 2 min	LMA C	30	93.02	7.37	0.0098 ***Significant***
	LMA A	30	87.16	9.50	
Post insertion at 5 min	LMA C	30	88.83	4.72	0.004 ***Significant***
	LMA A	30	83.94	7.58	

Heart rate, SBP, DBP and MAP were measured pre operatively and after insertion of the LMA at 1min, 2 min and 5 min. The actual values are documented in the tabular column.

Statistical analysis by student t test reveals $p < 0.05$ which is statistically significant.

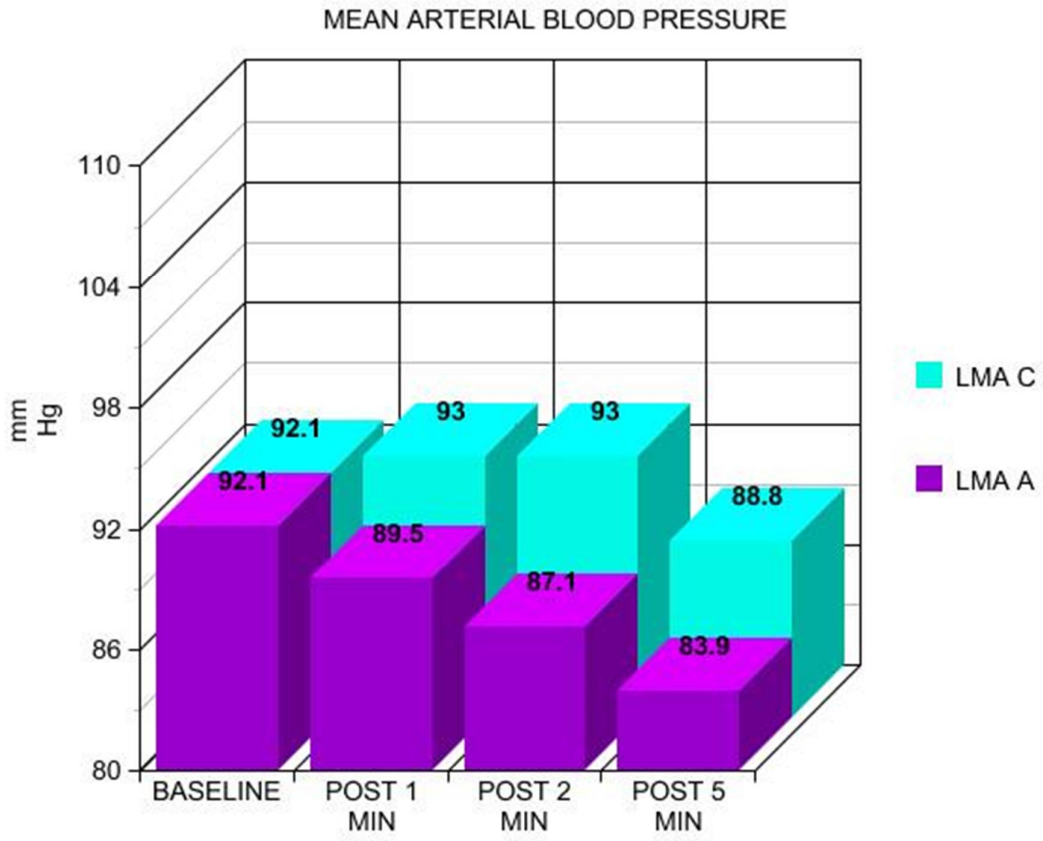

MEAN ARTERIAL BLOOD PRESSURE
110
104
98
92
86
80
mm Hg
92.1
93
93
88.8
92.1
89.5
87.1
83.9
BASELINE
POST 1 MIN
POST 2 MIN
POST 5 MIN
LMA C
LMA A

Table: 12 Blood staining of device

Group	Number of patients	Blood staining				P value
		Yes	%	No	%	0.068 Not significant
LMA C	30	3	10	27	90	
LMA A	30	2	6.67	28	93.33	

Blood staining after extubation denotes airway trauma by the device. It occurred in 3/30 cases with LMA Classic and in 2/30 cases with AMBU LMA.

Statistical analysis reveals p value (p = 0.068) which is statistically insignificant.

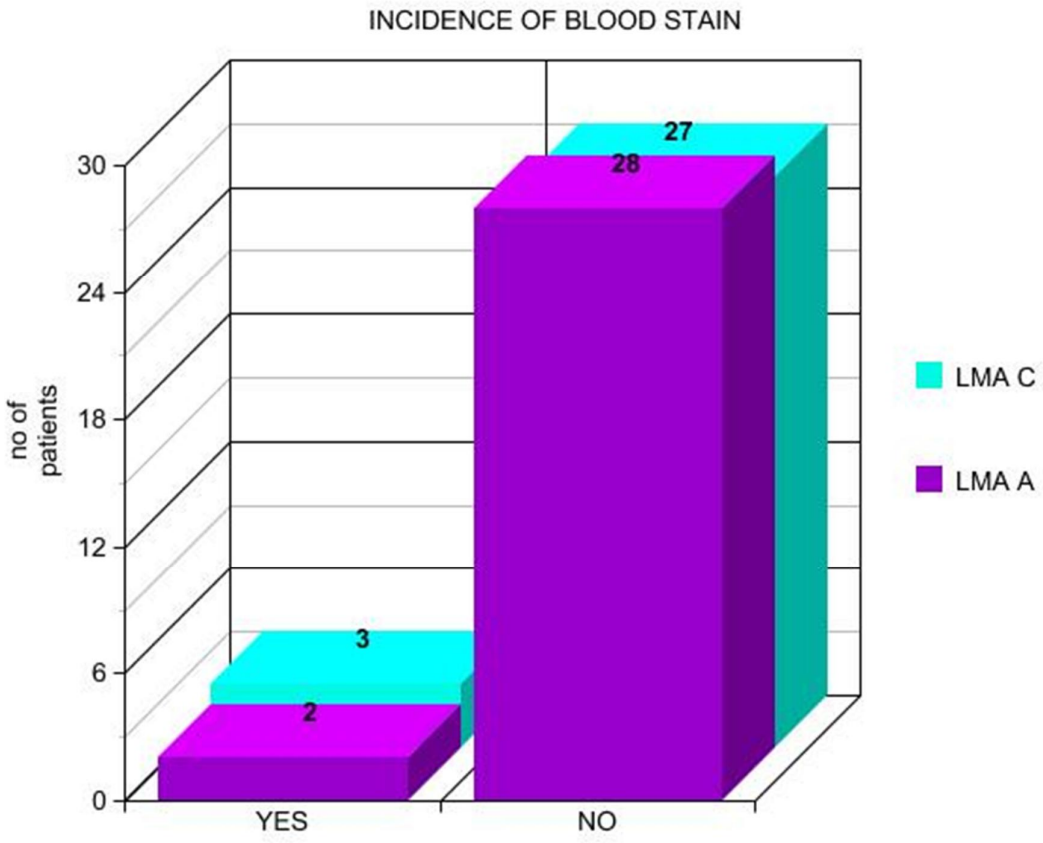
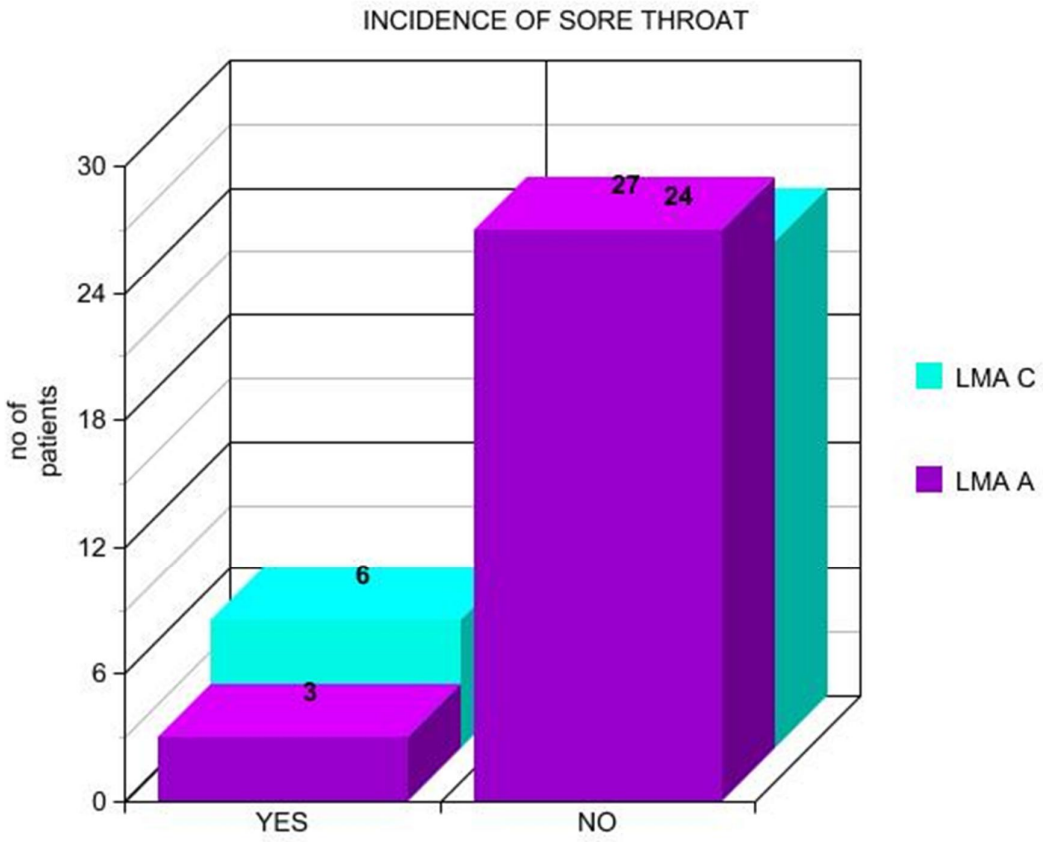

INCIDENCE OF BLOOD STAIN
no of patients
30
24
18
12
6
0
27
28
3
2
YES
NO
LMA C
LMA A

Table: 13 Incidence of sore throat

Group	Number of patients	Sore throat				P value
		Yes	%	No	%	0.462 Not significant
LMA C	30	6	20	24	80	
LMA A	30	3	10	27	90	

Sore throat occurred in 6 cases with LMA Classic and 3 cases with AMBU LMA. Statistical analysis reveals a p value (p = 0.462) which is statistically not significant.


INCIDENCE OF SORE THROAT
no of patients
30
24
18
12
6
0
27
24
6
3
YES
NO
LMA C
LMA A

DISCUSSION

AMBU LMA is a type of supraglottic airway device which is a disposable device, better conforming to the human anatomical airway.

This study is to compare the clinical performance of LMA Classic with the AMBU LMA.

Ease of insertion of airway device:

Insertion of AMBU LMA was easy in vast majoriy of population. In our study AMBU LMA is inserted with ease in 90% of patients and Classic LMA was inserted with ease in 63 % of patients.

This is in concurrence with the study conducted by **Sudhir et al**[16]. They compared AMBU LMA with Classic LMA as a cross over study and found that AMBU LMA had better ease of insertion compared to Classic LMA. **Hagberg et al**[2] conducted a multicenter study and found that AMBU LMA was easier and quicker to insert. **Kristine et al**[4] found that AMBU LMA scored 100 % and Classic LMA scored only 93 % in term of ease of insertion.

Number of attempts to successful placement:

AMBU LMA was successfully inserted in 100 % patients with the first attempt success rate of 93.3 %. Classic LMA was successfully inserted in 100 % with first attempt success rate of 83.3 %. The first attempt success rate was superior for AMBU LMA compared to the Classic LMA.

The study conducted by **Suzanna et al**[1] reported 87 % and 83 % first attempt success rate for Classic LMA and AMBU LMA respectively. The study conducted by **Genzwuerker et al**[8] reported 90 % and 94 % first attempt success rate with Classic LMA and AMBU LMA respectively.

The overall success rate in many previous studies is 100 %, and is achieved in 2 attempts.

Time taken for insertion of the airway device:

Securing an effective airway was rapid with AMBU LMA compared with Classic LMA. The time taken for securing the airway with AMBU LMA was 15.2 sec which was shorter than 24.77 sec taken for the Classic LMA group.

This was supported by **Suzanna A.B et al**[1]. The mean insertion time was found to be 40 sec for the Classic LMA group and 35 sec for the AMBU LMA group ($p = 0.008$).

Studies by **Miceli.L**[3] et al and other studies conclude that AMBU LMA took shorter time for insertion compared to Classic LMA.

The shorter insertion time can be extremely beneficial in difficult airway or in emergency situations.

Haemodynamic responses:

Heart rate, SBP, DBP and MAP after insertion were maintained better with AMBU LMA than the Classic LMA.

This is supported by the study conducted by **SY Ng et al**[32] .The study concludes stating that haemodynamic instability following insertion of either of the airway devices were similar. Many other studies came to the conclusion that haemodynamic responses were similar among AMBU LMA and Classic LMA.

Blood staining:

Incidence of blood staining found on the device due to airway trauma is comparable among both the devices.

Suzanna et al[1] evaluated the efficacy and found that blood staining was found in 22 % and 14 % in Classic LMA and AMBU LMA respectively which were comparable.

Sore Throat:

Incidence of sore throat were comparable among Classic LMA and AMBU LMA.

Kristine Faust et al[4] reported the incidence of sore throat of 10 % in AMBU LMA group and 13 % in Classic LMA group which were comparable.

AMBU LMA has the advantage of being a single use device. There is an increased tendency towards single use devices due to awareness that protein and bacteria persist on anaesthetic and surgical instruments following decontamination and sterilization. Being a single use device it can reduce or even eliminate this problem.

Our study has certain limitations. First, we studied a female population with normal airways undergoing elective minor gynaecological surgeries. The data collected cannot be extrapolated to the use of LMA classic and LMA AMBU in males. Second, blinding was not practically possible, which may be a possible source of bias. Finally, being a single use device the cost effectiveness was not addressed.

SUMMARY

From this Prospective, Randomized, Comparative single blinded case control study which evaluated the effectiveness of LMA Classic and AMBU LMA, it was found that.

The ease of insertion was superior for AMBU LMA compared to the Classic LMA

Number of attempts required for successful insertion of Classic LMA was more than that of AMBU LMA with a $p = 0.028$ which is statistically significant

The time taken for insertion of AMBU LMA was shorter compared to Classic LMA with a $p < 0.001$ which is statistically significant.

Haemodynamically there was significant difference between the two groups with regard to heart rate, systolic blood pressure, diastolic blood pressure and mean arterial blood pressure after insertion. AMBU LMA was found to have better hemodynamic stability compared to Classic LMA.

Blood staining on AMBU LMA and Classic LMA were comparable and was not statistically significant.

Incidence of post operative sore throat was comparable and was not statistically significant between AMBU LMA and Classic LMA.

CONCLUSION

AMBU LMA is an equally effective airway device to Classic LMA in gynaecological surgeries. It has potential advantages like easier and quicker to insert, better success rate at first attempt, lesser haemodynamic response and less airway trauma.

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INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No: 04425305301
Fax : 04425363970

CERTIFICATE OF APPROVAL

To
Dr. V. Bharath
PG in MD Anaesthesia
Madras Medical College, Chennai-3

Dear Dr. V. Bharath

The Institutional Ethics Committee of Madras Medical College reviewed and discussed your application for approval of the proposal entitled " A Prospective, randomized study to compare the effectiveness of AMBU Ima with classic Ima in gynaecological surgeries " No.13022012.

The following members of Ethics Committee were present in the meeting held on 22.02.2012 conducted at Madras Medical College, Chennai -3.

1.	Dr. S.K. Rajan, MD.FRCP.DSc	-- Chairperson
2.	Prof. Pregna. B. Dolia MD Vice Principal , Madras Medical College, Chennai -3	-- Member Secretary
3.	Prof. Md Ali. MD DM Prof & HOD, Dept. of MGE, MMC, Chennai -3	-- Member
4.	Prof Vasanthi MD Prof of Pharmacology, MMC, Ch-3	-- Member
5.	Prof. E. Dhandapani, MD Prof of Internal Medicine, MMC, Ch-3	-- Member
6.	Thiru. S. Govindasamy . BA.BL	-- Lawyer
7 .	Tmt. Arnold Soulina MA , MSW	-- Social Scientist

We approve the proposal to be conducted in its presented form

Sd /. Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report

Member Secretary, Ethics Committee

PATIENT CONSENT FORM

Study title : A Prospective, randomized study to compare the effectiveness of AMBU LMA with LMA Classic in Gynaecological surgeries.

Study centre: Department of Anaesthesiology, Govt. Kasturbai Gandhi Hospital for Women & Children, Chennai.

Participant name : Age: Sex: I.P.No:

I confirm that I have understood the purpose of procedure for the above study . I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety, advantage and disadvantage of the technique.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator ,regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to third parties or published , unless as required under the law . I agree not to restrict the use of any data or results that arise from the study .

Time:

Date: Signature / thumb impression of patient

Place: Patient name:

Signature of the investigator:

Name of the investigator:

GROUP LMA C										
SE:NO	NAME	AGE	IP NO	Wt	Ht	BMI	MMS	ASA	DIAGNOSIS	PROCEDURE
1	Shanthi	29	2140	62	158	24.83	I	I	Primary infertiliy	DHL
2	Subatra devi	25	2151	45	148	20.54	I	I	Primary infertiliy	DHL
3	Bhuvana	33	2441	50	145	23.78	I	I	Primary infertiliy	DHL
4	Banumathy	35	2257	68	152	29.43	I	I	Fibroid uterus	DH
5	Revathy	22	2320	61	144	29.41	I	I	AUB	DL
6	Rani	36	2323	44	149	19.82	I	II	AUB	DL
7	Bakkiyalakshmi	21	2087	60	153	25.63	II	I	Primary infertiliy	DHL
8	Sridevi	36	2086	47	149	21.17	I	I	Primary infertiliy	DHL
9	Amudha	37	1680	58	151	25.44	I	I	Primary infertiliy	DHL
10	Ammu	29	2487	44	143	21.52	II	I	Primary infertiliy	DHL
11	Sangeetha	25	2881	52	156	21.37	I	I	Primary infertiliy	DHL
12	Selvi	44	2895	46	148	21	I	II	Fibroid uterus	DH
13	Sundari	46	2693	54	155	22.48	I	I	AUB	DH
14	Rajeshwari	25	2481	47	149	21.17	II	I	Primary infertiliy	DHL
15	Rani	27	2927	57	159	22.55	I	I	Primary infertiliy	DHL
16	Kamala	43	2454	48	148	21.91	I	I	AUB	DH
17	Periyammal	45	2636	53	149	23.87	I	II	AUB	DH
18	Lakshmi	35	2633	49	155	20.4	I	I	AUB	DH
19	Pachiammal	46	2696	54	159	21.36	II	I	AUB	DH
20	Sumathi	37	2692	52	154	21.93	II	I	Fibroid uterus	DH
21	Thara	50	2967	41	145	19.5	I	II	AUB	DH
22	Indrani	32	2995	51	149	22.97	I	I	Secondary infertility	DHL
23	Bharani	50	3076	58	158	23.23	I	II	AUB	DH
24	Maheshwari	23	3072	52	143	25.43	I	I	AUB	DH
25	Malar	40	3085	62	159	24.52	I	I	Fibroid uterus	DH
26	Amudha	43	3149	55	154	23.19	II	I	AUB	DH
27	Johara bee	47	2690	49	150	21.78	I	II	AUB	DH
28	Entha	25	3136	63	161	24.3	I	I	Cu T Removal	DH
29	Sharmila begum	17	3397	67	159	26.5	II	I	Rt Ovarian cyst	DL
30	Daisy mary	37	3469	60	158	24.03	I	I	Fibroid uterus	DH

GROUP LMA A										
SE:NO	NAME	AGE	IP NO	Wt	Ht	BMI	MMS	ASA	DIAGNOSIS	PROCEDURE
1	Thulasi	26	3535	45	148	20.54	I	I	Primary Infertility	DHL
2	Eswari	45	3624	53	156	21.78	I	II	Fibroid uterus	DH
3	Chandhini	40	4049	60	158	24.03	II	I	Primary Infertility	DHL
4	Shanthi	27	3858	44	151	19.3	I	I	Primary Infertility	DHL
5	Manjula	38	3839	64	160	25	I	I	Primary Infertility	DHL
6	Sangeetha	25	11423	48	149	21.62	I	I	Primary Infertility	DHL
7	Nagamma	45	3980	60	159	23.73	II	II	AUB	DH
8	Gunasundari	32	11832	45	148	20.54	I	I	Primary Infertility	DHL
9	Hemamalini	30	4309	67	159	26.5	II	I	Primary Infertility	DHL
10	Pattu	30	4388	47	151	20.61	I	I	Primary Infertility	DHL
11	Anjali	25	4392	55	156	22.6	I	I	Primary Infertility	DHL
12	Radhika	26	6481	49	150	21.78	I	I	Rt Ovarian cyst	DH
13	Stella	40	6485	54	158	21.63	I	I	Fibroid uterus	DH
14	Devi	38	6488	57	149	25.67	I	I	Fibroid uterus	DH
15	Esther	34	4596	67	161	25.85	II	I	AUB	DH
16	Kanaga	40	4612	58	159	22.94	I	II	Fibroid uterus	DH
17	Shanthi	32	5200	53	149	23.87	I	I	Primary Infertility	DHL
18	Gracy	33	4181	51	148	23.28	I	I	Primary Infertility	DHL
19	Sangeetha	22	4915	59	154	24.88	II	I	Primary Infertility	DHL
20	Selvi	29	4982	44	149	19.82	I	I	AUB	DH
21	Alamelu	28	5046	67	159	26.5	I	I	AUB	DH
22	Vasugi	40	3538	64	159	25.32	I	II	Fibroid uterus	DH
23	Reethambal	36	3537	53	149	23.87	II	I	Fibroid uterus	DH
24	Gowri	36	3619	59	151	25.88	II	I	Fibroid uterus	DH
25	Sigamani	56	3457	47	146	22.05	I	II	PMB	DH
26	Malliga	55	3998	57	156	23.42	I	II	AUB	DH
27	Revathy	35	15789	55	155	22.89	I	I	AUB	DH
28	Malar	40	4393	43	145	20.45	I	I	AUB	DH
29	Indra	45	1685	44	146	20.64	I	I	AUB	DH
30	Lalitha	30	1749	56	155	23.31	I	I	Secondary Infertility	DHL

GROUP LMA C								
SE NO	HEART RATE				$ETCO_2$	INSERTION	ATTEMPTS	TTI
	Baseline	1 min	2min	5min				
1	78	86	88	79	39	1	1	22
2	80	89	92	78	36	2	2	25
3	81	70	72	74	38	2	1	24
4	89	77	78	80	35	1	1	21
5	76	82	84	80	34	1	1	21
6	70	68	69	70	39	1	1	20
7	76	74	72	72	36	2	1	24
8	78	88	86	80	39	1	1	23
9	81	90	91	85	37	1	1	26
10	80	73	73	70	36	1	1	26
11	78	82	85	80	36	2	2	28
12	78	74	73	72	38	1	1	22
13	78	85	88	79	34	2	1	26
14	69	70	68	68	36	1	1	23
15	80	72	71	71	37	1	1	25
16	78	86	88	84	39	2	1	26
17	76	88	90	83	38	2	2	27
18	72	80	82	80	39	1	1	22
19	64	68	69	68	35	1	1	27
20	70	78	80	77	36	1	1	26
21	77	79	80	82	38	2	2	31
22	79	84	85	82	38	1	1	23
23	76	75	74	72	37	2	1	24
24	75	82	83	78	36	1	1	26
25	77	73	72	70	38	1	1	24
26	79	83	85	78	39	2	1	28
27	80	74	72	72	36	1	1	23
28	77	84	85	77	38	1	1	25
29	76	77	78	78	36	1	1	26
30	79	84	82	78	38	2	2	29

GROUP LMA A								
SE NO	HEART RATE				$ETCO_2$	INSERTION	ATTEMPTS	TTI
	Baseline	1 min	2min	5min				
1	78	79	80	76	36	1	1	15
2	77	74	76	70	38	1	1	12
3	80	79	74	72	36	1	1	16
4	81	88	90	84	37	1	2	19
5	77	86	88	74	38	1	1	12
6	74	70	68	67	38	1	1	13
7	76	77	70	68	37	1	1	15
8	76	77	80	74	37	1	1	14
9	80	76	75	75	36	1	1	16
10	78	77	72	70	39	1	1	16
11	79	85	88	78	37	1	1	13
12	75	79	77	78	37	1	1	13
13	64	70	72	71	38	2	1	17
14	74	77	78	72	37	1	1	16
15	73	88	92	80	37	1	1	15
16	77	76	70	67	36	1	1	12
17	75	77	78	78	38	1	1	18
18	79	80	76	72	36	1	1	12
19	75	70	67	68	38	1	1	14
20	80	70	68	67	36	1	1	13
21	67	78	80	75	38	1	1	15
22	64	66	68	70	37	1	1	16
23	82	92	96	82	37	2	2	25
24	82	78	76	74	36	2	1	17
25	76	77	76	80	37	1	1	19
26	79	75	72	70	37	1	1	16
27	75	70	77	76	36	1	1	14
28	76	70	68	66	37	1	1	15
29	79	79	80	76	36	1	1	13
30	80	70	72	72	36	1	1	15

GROUP LMA C												
	Baseline			1 min after insertion			2 min after insertion			5 min after insertion		
S NO	systolic	diastolic	mean	systolic	diastolic	mean	systolic	diastolic	mean	systolic	diastolic	mean
1	131	83	99	144	90	108	144	88	107	121	78	92.3
2	116	78	90.7	124	82	96	127	84	98.3	110	74	86
3	128	84	98.7	110	72	84.7	110	73	85.3	106	70	82
4	136	78	97.3	116	74	88	108	72	84	104	71	82
5	116	74	88	124	78	93.3	126	80	95.3	121	79	93
6	121	79	93	118	74	88.7	114	73	86.7	112	73	86
7	124	80	94.7	117	76	89.7	114	75	88	113	76	88.3
8	128	81	96.7	134	84	101	136	85	102	126	81	96
9	118	79	92	121	81	94.3	124	81	95.3	116	78	90.7
10	114	76	88.7	108	72	84	102	71	81.3	104	71	82
11	118	77	90.7	116	77	90	108	72	84	119	79	92.3
12	128	81	96.7	116	78	90.7	112	77	88.7	110	76	87.3
13	118	79	92	128	84	98.7	130	85	100	124	80	94.7
14	108	74	85.3	110	75	86.7	111	76	87.7	108	75	86
15	113	75	87.7	108	73	84.7	106	71	82.7	104	71	82
16	112	74	86.7	121	81	94.3	124	82	96	118	79	92
17	121	80	93.7	132	85	101	134	86	102	128	84	98.7
18	117	74	88.3	110	72	84.7	104	68	80	103	69	80.3
19	114	76	88.7	116	77	90	118	78	91.3	113	74	87
20	118	77	90.7	121	80	93.7	122	80	94	116	76	89.3
21	123	80	94.3	125	81	95.7	128	82	97.3	119	78	91.7
22	114	75	88	121	79	93	124	81	95.3	116	76	89.3
23	118	77	90.7	114	74	87.3	113	74	87	110	72	84.7
24	121	79	93	125	81	95.7	128	82	97.3	118	77	90.7
25	124	78	93.3	116	75	88.7	112	73	86	110	73	85.3
26	117	76	89.7	124	81	95.3	128	82	97.3	119	79	92.3
27	128	78	94.7	112	77	88.7	110	75	86.7	106	74	84.7
28	114	76	88.7	120	79	92.7	123	81	95	119	79	92.3
29	124	81	95.3	131	83	99	134	84	101	123	80	94.3
30	114	76	88.7	121	81	94.3	124	81	95.3	119	78	91.7

GROUP LMA A												
	Baseline			1 min after insertion			2 min after insertion			5 min after insertion		
S NO	systolic	diastolic	mean	systolic	diastolic	mean	systolic	diastolic	mean	systolic	diastolic	mean
1	116	78	90.7	107	72	83.7	98	67	77.3	95	65	75
2	121	82	95	108	76	86.7	99	69	79	96	68	77.3
3	131	83	99	119	76	90.3	110	74	86	109	75	86.3
4	136	80	98.7	141	82	101.7	131	78	95.7	129	78	95
5	121	74	89.7	130	79	96	133	81	98.3	126	77	93.3
6	108	69	82	96	62	73.3	95	63	73.7	98	64	75.3
7	127	77	93.7	130	78	95.3	128	78	94.7	121	76	91
8	124	78	93.3	120	76	90.7	116	72	86.7	106	68	80.7
9	123	76	91.7	122	74	90	124	74	90.7	108	70	82.7
10	110	70	83.3	102	67	78.7	103	66	78.3	100	64	76
11	116	76	89.3	124	82	96	126	83	97.3	122	81	94.7
12	124	79	94	110	72	84.7	106	68	80.7	104	68	80
13	128	82	97.3	135	84	101	133	85	101	120	79	92.7
14	118	76	90	122	78	92.7	123	78	93	120	76	90.7
15	129	83	98.3	138	88	104.7	142	90	107.3	130	80	96.7
16	129	80	96.3	130	82	98	118	76	90	110	71	84
17	119	76	90.3	104	72	82.7	96	68	77.3	92	62	72
18	114	74	87.3	102	68	79.3	94	61	72	90	59	70
19	121	81	94.3	116	76	89.3	112	72	85.3	110	69	82.7
20	116	81	92.7	110	75	86.7	108	74	85.3	102	72	82
21	110	76	87.3	124	82	96	126	82	96.7	116	78	86.7
22	112	77	88.7	116	79	91.3	117	78	91	120	80	93.3
23	132	81	98	138	84	102	142	85	104	126	77	93.3
24	129	82	97.7	118	77	90.7	114	74	87.3	110	72	84.7
25	132	79	96.7	116	78	90.7	114	76	88.7	110	74	86
26	110	70	83.3	104	67	79.3	98	64	75.3	97	64	75
27	113	67	82.3	107	64	78.3	98	60	72.7	102	61	74.7
28	124	82	96	106	74	78	104	72	82.7	102	72	82
29	118	78	91.3	110	72	84.7	104	68	80	103	69	80.3
30	125	81	95.7	118	78	91.3	113	74	87	110	72	84.7

	GROUP LMA C		GROUP LMA A	
S NO	SORE THROAT	BLOOD STAIN	SORE THROAT	BLOOD STAIN
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
4	yes	yes	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	yes	0
8	0	0	0	0
9	yes	0	0	0
10	0	0	0	yes
11	0	0	0	0
12	0	0	0	0
13	0	0	0	0
14	0	0	0	0
15	yes	0	0	0
16	0	0	0	0
17	0	yes	0	0
18	0	0	0	0
19	0	yes	yes	yes
20	0	0	0	0
21	yes	0	0	0
22	yes	0	0	0
23	0	0	0	0
24	0	0	0	0
25	0	0	0	0
26	0	0	yes	0
27	0	0	0	0
28	0	0	0	0
29	0	0	0	0
30	yes	0	0	0

PROFORMA

DATE: ROLL NO: AIRWAY DEVICE:

NAME:

AGE: SEX: IP NO:

DIAGNOSIS:

SURGICAL PROCEDURE DONE:

Ht: CVS: HB:

Wt: RS:

AIRWAY: MMC - IID - DENTITION -

PRE OP ASSESSMENT:

HISTORY: Any Co-morbid illness

H/O Documented Difficult Airway

H/O previous surgeries

MEASURES OF STUDY OUTCOME:

INTUBATION RESPONSE:

HR SBP DBP MAP

PRE OP:

POST INTUBATION:

1 MIN:

2 MIN:

5 MIN:

10 MIN:

EASE OF INSERTION: EASY DIFFICULT

NO OF ATTEMPTS:

INSERTION TIME:

BLOOD STAINING OF LMA Classic/AMBU LMA:

POST OP SORE THROAT

INTRODUCTION

Supraglottic airway devices are devices that ventilate patients by delivering anaesthetic gases and oxygen above the level of vocal cords thereby avoiding the disadvantages of endotracheal intubation. Supraglottic airway devices have the advantages of avoiding laryngoscopy, better tolerance by the patients, lesser hemodynamic perturbations, lesser invasiveness of the respiratory tract, easier placement of the device, airway free from manipulation, lesser complications like sore throat and easier, quicker control of airway even by inexperienced personal.

Laryngeal mask airway is a type of Supraglottic airway device